IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION AT CLEVELAND

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	Case No. 1:17-md-2804
CASE TRACK THREE	**VOLUME 18** JURY TRIAL *(Pages 4488 - 4764)*
	October 28, 2021

TRANSCRIPT OF JURY TRIAL PROCEEDINGS

HELD BEFORE THE HONORABLE DAN AARON POLSTER

SENIOR UNITED STATES DISTRICT JUDGE

Official Court Reporter: Heather K. Newman, RMR, CRR
United States District Court
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Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

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ALSO PRESENT:	David Cohen, Special Master

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I N D E X

PAGE

(On the record at 8:45 a.m.)

COURTROOM DEPUTY: All rise.

THE COURT: Everyone can be seated.

I think I got an e-mail that defendants have a motion that they wanted to make.

MR. DELINSKY: Yes, Your Honor. Eric Delinsky for CVS.

Your Honor, this pertains to directed verdict, and we took to heart your comments yesterday on timing, and we are going to be submitting motions that set forth the ground I want to talk to you about as well as many other grounds, but there is a -- an immediacy to one ground that's important to what the remainder of trial looks like, which is why we wanted to bring it to your attention as promptly as possible.

And the issue, Your Honor, are the distribution claims. Under Rule 50, of course, directed verdict can be granted on an issue, and this is one of the issues in the case, and I think on behalf of all defendants, all three of us, we do move, and we'll supplement in our motion, which will include other grounds for directed verdict on distribution grounds. And here's the bases, Your Honor. It's 60 seconds.

Number one, I think as Your Honor remembers, there was an expert on distribution who not only opined on systems, on

each of our systems, but also set forth metrics to identify potentially suspicious orders. That expert was not called. His opinions are not in evidence. That was Mr. Rafalski.

The other piece of evidence that we saw in the build-up to trial was the testimony of Dr. McCann, who then in his expert reports would run those metrics to identify potentially suspicious orders that Mr. Rafalski has set and opined on in his expertise as a former DEA diversion investigator. Dr. McCann did not testify about any orders or any particular shipments, and he didn't apply Mr. Rafalski's metrics to identify potentially suspicious orders.

And then finally, pertinent to the discussion that we had I believe it was the -- 2 nights ago, 2 evenings ago, no summaries of shipment data from the ARCOS database were submitted into evidence. All that was admitted through Mr. McCann was summaries of dispensing data and dispensing.

So, Your Honor, I think you'll understand why we are raising it. There is a situation of it, absent of proof here, that's so basic that there isn't even evidence that any defendant shipped into the two counties to any pharmacy in the county because there is no evidence of a single shipment, much less one that could be characterized as suspicious.

So, Your Honor, that's the basis was. There really is

no more to it. I'm happy to answer questions, and I imagine that Pete or Mark will have something to say about that, but it's that simple, Your Honor.

And, Your Honor, there is one other add-on point --

08:49:22 And I'm sorry, Pete. I'm sorry. I wasn't quite done.

-- and it's not a point of legal analysis, it's a point of practicality, and this is what compels us to make this motion this morning. This impacts the remainder of trial. It impacts, obviously, jury instructions, and it

08:49:41 impacts what defendants do in their defense, who they call, what they ask witnesses about, what they ask experts about, so we think there's a -- we think it's important to raise this issue and obtain the Court's views in a timely way. It could streamline things moving forward.

08:50:05 And I just -- before I stop talking, Your Honor, there's one added issue, is at least one of the notes in my read of it from the jurors has reflected some confusion. It talked about a duty to report prescriptions. I don't think they used suspicious prescriptions to DEA, that seemed to be

08:50:27 transposing the SOM requirement in the CFR on the dispensing-based requirements. It's totally understandable confusion. I don't mean to be disparaging or derogatory of any jurors in any way whatsoever. I think most normal people would confuse that. But it's yet another reason why

08:50:45 if it's not in the case and there's no evidence to support

it, and we believe there isn't, it's very important for simplicity and clarity to the jury to get it out right now.

THE COURT: All right.

MR. STOFFELMAYR: Kaspar Stoffelmayr for Walgreens.

08:51:06

You know, we join Mr. Delinsky's motion, and all I would add is I think based on the record we have today, perhaps I would disagree, but perhaps, you know, you could say, we'll argue night and day -- based on evidence entirely from fact witnesses so far -- but we'll argue night and day about whether Walgreens' systems are the right ones, whether they did a good enough job to detect orders, to report orders, to hold orders, to do due diligence, again, we could, you know, maybe have that argument, but the bottom line is there is exactly zero evidence about any supposedly suspicious order being shipped to anywhere in Ohio, certainly not these two counties. There were experts who were supposed to present that kind of evidence. They weren't called.

08:51:21

08:51:36

So at this point we're just sort of left, like, why would we bring witnesses or call witnesses to talk about systems intended to block shipments of which there is no evidence in the first place?

08:51:50

MR. MAJORAS: Your Honor, John Majoras.

As for Walmart, we also join the motion for the same

08:52:08

reasons, and I'll point out specifically to Walmart, there's not been a single piece of evidence or testimony even related to our distribution system. No one would know -- even know where our distributors are located based on the 08:52:21 evidence that's come into the record. So certainly in our case, and likewise with the other defendants, but in our case, there's just been no evidence whatsoever. The only Walmart witness called to testify is Mr. Nelson. He's only on the dispensing side. Those were the only questions he 08:52:38 had. There's zero evidence with respect to our systems and with respect to distribution.

THE COURT: All right. Well, I guess if the plaintiffs want to briefly respond, I think I'm going to want a written response from the plaintiffs highlighting 08:52:54 what evidence they believe is in the record on distribution.

I agree, the overwhelming amount of the evidence has focused on -- on prescribing practices and prescriptions filled. All right? And I said, you know, a year ago that most likely there's no independent harm from shipping 08:53:23 to yourself, because if all that happens is the pills stay in a warehouse or a pharmacy, nothing happens. The only way anything gets out in the community is if they're either stolen, and that's not what the case is about, or they're dispensed. So the harm is clearly going from the 08:53:42 dispensing, but I agree, there hasn't been much testimony

about anything relating to the shipments other than the pharmacies shipped to themselves.

So I -- if the plaintiffs want to briefly respond, I want to, you know, move forward at 9 o'clock, but I think I'm going to want a written response from the plaintiffs as to whether they're still pursuing their -- the distribution claims and what evidence they have that they've put in that the distribution claims were illegal or intentionally defective or inadequate.

08:54:25 MR. WEINBERGER: Your Honor, we will provide a written response.

Do you want to give us a time frame within which you would like to have it?

THE COURT: Well, seems to me no later than 08:54:40 Monday morning.

MR. WEINBERGER: That's fine.

THE COURT: But you should strongly consider if you're -- I mean --

MR. WEINBERGER: I will say, Your Honor, that 08:54:49 what is unique about the distribution case, unlike the big 3 distributors, of course, is that these defendants were distributing to themselves primarily hydrocodone from --

THE COURT: Well, I understand that, but I -- I have -- I don't recall any evidence -- any evidence from 08:55:08 fact witnesses identifying suspicious shipments, orders or

shipments.

MR. WEINBERGER: That's exactly the point, Your Honor.

THE COURT: Or even in total.

08:55:20 MR. WEINBERGER: They had systems in place that didn't identify them, and there was -- there is evidence in the record for substantial periods of time from 2006 until 2012 with respect to these defendants that they didn't have an operating system that was in compliance with

08:55:42 the letters issued by Mr. Rannazzisi in 2006 and 2007, but as I said, we'll give you the details on that.

THE COURT: Well, if that's -- basically their claim is, hey, you were required to have a system and the evidence is you had no system at all, well, that could be

08:56:00 enough. I mean, if you have no system at all, it can't be inadequate -- it can't be an adequate one.

MR. DELINSKY: Your Honor --

THE COURT: I mean, that's their -- if that's their claim, then I'll -- but --

08:56:11 MR. DELINSKY: But, Your Honor, I think our rejoinder to that, and I understand we'll receive briefing on that and I want to speak to it, but our rejoinder to that is you still need evidence of an order.

THE COURT: Well, there has been evidence of

08:56:24 an order.

MR. DELINSKY: No, Your Honor, there hasn't. There's not a shred of evidence attached to CVS that CVS shipped an order into Lake or Trumbull County.

THE COURT: Yes, there has been. The witness has testified that that's how all the pharmacies got their --

MR. DELINSKY: No. Your Honor --

MR. MAJORAS: Your Honor, we'll brief this.

THE COURT: All right. Fine. I mean, that -- you're not going to win on that. There's evidence that that's how all these -- all these drugs got into the defendants' pharmacies, that they were shipped by themselves, by their corporate -- corporate distribution chain.

MR. STOFFELMAYR: Judge, if I may --

THE COURT: There hasn't been any -- I agree, there's been no evidence that any particular order or shipment was defective, inadequate, et cetera, there's been -- so -- but there certainly has been testimony that that's how all the pharmacies got these -- got the drugs.

MR. STOFFELMAYR: Judge, may I explain that I think where we're coming from?

We're not denying that orders were shipped to pharmacies. If the claim is -- let's say hypothetically -- I don't want to engage in the part where there's a -- let's

say hypothetical there was no system -- which is not correct -- let's say hypothetically there was no, zero, just zip for systems and half the orders should have been identified and blocked but were not. No one has said that. No one has said how many orders should have been identified and blocked but we're were.

But let's say someone came in and said there was no system and I figured out that as a consequence half of your orders should never have been shipped. Even if somebody were able to come in and say that, which they haven't, no one has said that the orders that went to Lake and Trumbull Counties were in the half that it should not have been shipped or the half that it was fine to ship.

That's the missing -- from our perspective, that's the clear gap in the evidence. Everything else maybe we can argue about, but that last part, there's just -- no one has even tried to say that.

MR. LANIER: With due respect, Your Honor we'll brief this.

THE COURT: All right, well --

MR. LANIER: But it's not -- our whole point is is that these stores were putting out pills in volumes they shouldn't have been putting them out, should have alerted them as distributors, should have alerted them as pharmacists, and, frankly, they ignored it on both levels.

And the whole point of distribution is that it's supposed to keep in check these stores from putting out massive amounts of pills. It did not, and they didn't have a system.

08:58:43 THE COURT: That may be sufficient to go forward, but -- all right, so --

MR. MAJORAS: Your Honor, just from Walmart's perspective --

THE COURT: Well, I'll just say a response by

08:58:53 Monday morning and then --

MR. LANIER: That would be great, Judge.

THE COURT: -- when do the defendants want to -- I mean, it's an oral motion. I don't -- I mean, I don't know if you want to -- I mean, you've made it orally.

08:59:07 Why don't you just say when do you want to have your reply rather than --

MR. DELINSKY: Your Honor --

THE COURT: Your reply will be focused.

MR. DELINSKY: Here's the complexity,

08:59:16 Your Honor, is this could impact Monday witnesses.

THE COURT: Well, I can't help that, Mr. Delinsky. All right?

MR. DELINSKY: What I'm asking is could we expedite the briefing? We can turn around something

08:59:22 really --

THE COURT: No. This is important enough, I want it -- I want a thorough response. All right? All right? I think I've crystalized the issue. There has not been any testimony -- there's no dispute, there's been no testimony identifying any particular order or shipment as suspicious. The plaintiffs -- you know, they're not going to say that in their brief because there hasn't been any. We know that. So they're not relying on any particular shipment or order. It's the -- so --

08:59:55 When do you want to respond? You tell me. You'll get their -- you'll get their brief on Monday morning.

MR. DELINSKY: We'll respond in 24 hours, Your Honor.

May we reserve the right to recall witnesses who may 09:00:07 be called on Monday --

THE COURT: Sure.

MR. DELINSKY: -- depending on the Court's ruling.

THE COURT: I -- I have no problem -- I don't 09:00:13 even think you need my permission.

MR. DELINSKY: Okay. I just wanted to --

THE COURT: As long as they're you're people.

MR. DELINSKY: Okay.

THE COURT: And as long as it's not 09:00:19 repetitive.

MR. DELINSKY: No.

THE COURT: But it wouldn't be. If you -- you can always recall someone if something new comes up.

MR. DELINSKY: Okay.

09:00:26 THE COURT: Either side. I don't think there's -- I'm not aware of a rule that prohibits that, is there?

MR. DELINSKY: No. No, Your Honor. Okay. Thank you, Your Honor.

09:00:33 THE COURT: That's fine.

MR. DELINSKY: Is 24 -- I'm looking at my co-defendants.

Does 24 hours --

THE COURT: I mean, if you want --

09:00:40 MR. DELINSKY: No, Your Honor. 24 hours.

MR. MAJORAS: There's no evidence of Walmart, Your Honor. I should be able to respond quickly.

THE COURT: Okay. So we'll have the plaintiffs' response on -- by Monday morning and Tuesday

09:00:49 morning the defendants, and then I will -- I will address it.

MR. DELINSKY: Thank you, Your Honor, and thank you for hearing us.

THE COURT: Okay. Did you look at the

09:01:01 exhibits for Ms. Toiga? If not we can take it up later.

That's the only one that --

MR. DELINSKY: I believe. . . I'm looking at Maria.

Was anything sent over to you? Was a proposal sent over to you?

MS. FLEMING: We got something. We're waiting to hear back from Laura.

MR. DELINSKY: Okay. Yeah, so we sent over something last night, Your Honor, and I don't think it's fair to ask plaintiffs to respond. So why don't we --

THE COURT: All right. You're still working on it.

MR. DELINSKY: Yes.

THE COURT: All right. My view is if the document was -- if she was shown it in the deposition and she knew something about it, presumptively it should come in. There has to be something redacted, fine.

Okay. Okay. I think we can bring in the -- bring in the jury then.

And I'll just say that my -- I have been working on the jury instructions, and I'm going to think later today we'll send the latest draft out to counsel.

MR. WEINBERGER: We actually got something from --

THE COURT: Oh, was it sent?

SPECIAL MASTER COHEN: Yeah. I sent it last night, Judge. There were some minor tweaks -- minor tweaks --

THE COURT: All right. It was sent last night. So, again, you should --

MR. LANIER: You're so fast you're ahead of yourself.

THE COURT: Yeah. Well, Special Master Cohen is.

09:02:25 At this point all I want from counsel, if you there's a 6th Circuit or Supreme Court or Ohio Supreme Court case that says that what I propose to say is wrong, I certainly want to know about it, or if you think that something just isn't clear and it would -- and the language confuses the

09:02:46 jury. I want to hear about that. Okay.

(Jury returned to courtroom at 9:04).

THE COURT: Good morning. Please be seated, ladies and gentlemen.

All right. Defendants may call their next witness,

09:04:39 please.

MR. SWANSON: Good morning, Your Honor.

Walgreens calls Mr. George Pavlich, a former agent for the Ohio Board of Pharmacy who we're calling over Zoom.

And if I may, Your Honor, I have a transcript and some

09:04:55 exhibits for the Court and for the record.

THE COURT: All right. Very good. Thank you, Mr. Swanson.

Okay. Good morning, sir. Can you hear me okay, Mr. Pavlich?

09:05:31 THE WITNESS: I can.

THE COURT: Okay.

THE WITNESS: I can.

THE COURT: Okay. Good morning. Thank you for getting available. If you could raise your right hand,

09:05:36 sir.

Do you swear or affirm that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth under pain and penalty of perjury?

THE WITNESS: I do.

09:05:46 THE COURT: Thank you very much.

All right, Mr. Swanson. You may proceed.

MR. SWANSON: Good morning, Your Honor.

Good morning, members of the jury.

May it please the Court. May I proceed, Your Honor?

09:05:55 THE COURT: Yes.

MR. SWANSON: Thank you.

DIRECT EXAMINATION OF GEORGE P. PAVLICH

BY MR. SWANSON:

Q Good morning, Mr. Pavlich. Could you please state

09:05:59 your full name for the jury?

A George Paul Pavlich, P-a-v-l-i-c-h.

Q Mr. Pavlich, my name is Brian Swanson and I represent Walgreens.

How are you this morning, sir?

09:06:13 **A** I'm alive and well.

Q We'll take it, right?

Sir, you and I have not met before; is that right?

A Not that I recall.

Q Well, not that I recall either, so we're on the same

09:06:25 page there, at least.

And, in fact, we haven't even spoken before about a minute ago; is that right?

A Yes.

Q Okay. Well, sir, I appreciate you getting online and

09:06:39 speaking with us today. I understand you're calling in from your home?

A Yes, I am. My office in my home.

Q Okay. Your home office, in, is it Poland, Ohio?

A Yes, it is.

09:06:53 **Q** And just to be sure, can you see and hear me okay? I can see you just fine, but can you see me?

A I see someone standing at -- yes. I can see you.

Q All right. That's me. I'm the one -- I'm the one talking to you.

09:07:09 And I hope that you've been joined by one of my

colleagues who's there to pitch in with some documents or other assistance if you need it.

A Gabe?

Q Yeah. I hope Gabe Levin is there. He left before light this morning. Did he make it?

09:07:22

A Yes. Him and Rachel are both here.

Q Okay. Terrific. Thank you.

And I'm going to do my best as we get into some documents to put them on the screen and make sure you can see them clearly, but if you want to look at a paper document or at the screen, that's totally your choice.

09:07:34

Okay?

A Okay. I have paper documents here too.

Q Terrific. Well, this is sort of new for everyone, so if there are any issues, you just give us a shout. Okay?

09:07:49

A Okay.

Q All right. Let's -- let's get going.

I understand, sir, that your currently retired; is that right?

A Yes, since 2012.

09:07:59

Q Okay. 2012. Can you tell us where you retired from?

A The Ohio State Board of Pharmacy. I was an agent assigned to Northeast Ohio.

Q And can you tell us how long -- so is it a field agent, was that your title?

09:08:18

A Yes. I worked in the field. I was with the Youngstown Police Department 10 years, 8 of it in narcotics, and then in 1987 I took a position with the Ohio State Board of Pharmacy and worked primarily in Northeast Ohio but I was sent all over the state. And I retired in March 1st, 2012.

Q Okay. So let me pause there and maybe we can back up and take it chronologically. And I want to go back to start in college, if I may.

You have a degree from Youngstown State University; is that right?

A Yes, in criminal justice.

Q Youngstown State Penguins, I understand, is that. . .

A Yep. They're still the Penguins.

Q I looked it up this morning. I was -- do you know why they're the Penguins?

A The only thing I know is they had a penguin on campus when I went to school there.

Q All right.

A Other than that, I have no idea.

Q Like a live one?

A A live one.

Q Got it.

A No. It was a live one.

Q Okay. And I think I heard your major you said was criminal justice?

A Yes.

Q What year was that?

A '74.

Q '74. Your first job out of college?

09:09:43 **A** First job in law enforcement was with the Youngstown Police Department in 1980 -- no, 1977.

Q And what was your first position with the Youngstown PD?

A I was a patrolman in parole division for approximately 09:10:00 two years.

Q After those two years as a patrolman, is that when you got into the narcotics division?

A I had a short term in the juvenile division, and then I went to the special investigation strike force narcotics 09:10:16 unit. I remained there until I left in '87.

Q So that was in or around '79 or '80 you became a member of the narcotics team?

A Yeah. '79.

Q Got it. Were you a plain clothes officer?

09:10:37 **A** Yes.

Q Did you have a special focus with the narcotics team, were you into --

A Pharmaceuticals was my special focus.

Q And was that in the Youngstown area you were focused 09:10:52 on pharmaceutical investigations?

A Youngstown primarily, but it expanded into all of Mahoning County. I had a commission with them during that time.

Q And can you tell us what you do as a plain clothes officer doing pharmaceutical drug investigations?

A Pretty much follow up on complaints as an investigative officer, write search warrants, provide documents to prosecutors, and with their assistance, try to obtain a conviction.

Q All right. I think if my timeline is correct, you held that position with the narcotics group for about 8 years in Youngstown?

A Yes. 10 years total with Youngstown Police Department.

Q You joined the Ohio State Board of Pharmacy in 1987?

A That is correct.

Q And I think you said you retired as a field agent. Was that the job also that you were hired into?

A Yes.

Q And if my math right, that's about 25 years you spent with the Ohio Board of Pharmacy?

A Yes, 35 total.

Q 35 total in law enforcement, 25 of which was at the Ohio Board of Pharmacy?

A Correct.

Q Thank you.

And I want to pause here for a moment because the jury here has heard about the Board of Pharmacy, but they haven't yet heard from a field agent.

09:12:33 And the work, sir, that you do, so I want to ask you both about the Board of Pharmacy and also your role within the Board of Pharmacy. Okay?

A Sure.

Q Terrific.

09:12:46 Starting with the Board of Pharmacy, is the Ohio Board of Pharmacy responsible for administering and enforcing the Drug Laws of Ohio?

A Yes, they are.

Q Is the Ohio Board of Pharmacy charged with preventing,

09:13:04 detecting, and investigating diversion of dangerous drugs, including controlled substances?

A Yes.

Q And we've heard a lot about diversion, but I'm interested from a field agent, what's your definition of

09:13:19 diversion of legal drugs?

A The prescribing, the dispensing, the administering, and the use of narcotics or dangerous drugs, which would be prescription drugs for illicit purposes.

Q And we talked about some of the roles of the Board of

09:13:48 Pharmacy in preventing, detecting, and investigative

diversion.

Are there other roles, in your 25 years there for the Board of Pharmacy, that you think are important to relate or articulate for us?

09:14:03 **A** I can't speak of the Board of Pharmacy as of today, but during my career we had strong enforcement, we conducted inspections of all licensed facilities, whether it be a pharmacy, a doctor's office, a fire department. We licensed these facilities, and we also strongly investigated street

09:14:30 people, the very common person who would pass a bad prescription, things of that sort. We're quite involved.

Q Thank you.

MR. SWANSON: Your Honor, this is new to me. There's apparently a call coming in -- okay.

09:14:46 BY MR. SWANSON:

Q Sorry, Mr. Pavlich. We had a little technical glitch there, but I think I heard your answer and I want to follow up.

This case, as you may know, focuses on pharmacies, so

09:14:57 most of my questions are going to focus on pharmacies and pharmacists and the role of the Board of Pharmacy vis-a-vis those entities. Okay?

A Sure.

Q I think you said that the Ohio Board of Pharmacy

09:15:15 licenses pharmacies.

Did I hear that right?

A Yes.

Q So in order to dispense a medication, including a Class 2 medication like an opioid medication, a pharmacy has to be licensed by the Board of Pharmacy; right?

A Yes. They would have a terminal distributor's license and they would also have a federal license for purposes of the controlled substance.

Q I've heard -- I've seen that term in some documents, a terminal distributor license. Is that just the same thing as a pharmacy, or are there differences?

A No. A terminal distributor license would be one for the terminal use of the drug. In other words, they bring it into the pharmacy and it terminates when it goes to the patient.

Q Understood.

So a pharmacy, I think you said, not only has to be licensed in Ohio by the Ohio Board of Pharmacy, but also by a federal entity, and that's the DEA, they register with the DEA?

A Yes.

Q The license that a pharmacy in Ohio has with the Board of Pharmacy, does that need to be periodically renewed?

A Yes. I believe it's every year, but I don't know as of current status.

Q At least when you were there up until 2012, a pharmacy had to renew their license with the board every year?

MR. WEINBERGER: Objection, Your Honor. I'm being liberal, but there's a lot of leading questions here.

09:16:46 THE COURT: Well --

MR. SWANSON: I can ask it again.

THE COURT: I think they've been okay so far, but I'll watch.

You can answer, sir.

09:17:01 BY MR. SWANSON:

Q My question, sir, is up until the time you left the board of pharmacy in 2012, did a pharmacy need to renew its license with the Board of Pharmacy every year?

A Yes, they did.

09:17:11 **Q** Do you know what was required for the Board of Pharmacy to license a pharmacy in Ohio?

A There were a lot of requirements, from security to a licensed pharmacist professional signing for the license, to, you know, a structure, recordkeeping, numerous

09:17:39 requirements.

Q I think we're going to touch on some of those as we proceed, so if others come to mind as we're talking about those, you just go ahead and raise those. Okay?

A Okay.

09:17:50 **Q** Does the -- does the Board of Pharmacy also license

pharmacists?

A They do.

Q Can you tell us what the requirements are from the Board of Pharmacy at least while you were there to license a pharmacist?

A They were required to graduate from a licensed university with a degree in pharmacy, and then it became PharmD degree, I think that was a 6-year degree, the other one was a 5-year degree when I was there. They would have to pass their board prior to being licensed and then they had CE -- or continuing education requirements to maintain that license.

Q Did the pharmacists need to have their license renewed or was it as long as they were consistent with their continuing education requirements they could reup?

Do you know?

A I don't remember if it was every year or every two years, every three years, the pharmacists would relicense. I believe it was in September. It was possibly every year, but I'm not clear on it.

Q Did the -- did the Ohio Board of Pharmacy and in your role, did you perform inspections of pharmacies?

A Yes. We were required to do a specific number every year on top of all of our investigations and other administrative regulatory requirements.

Q Do you remember what that number was, sir?

A I want to say 50, but I'm to the sure.

Q Okay. Well, we'll take -- we'll take 50.

And I just want to make one point of clarification. You mentioned inspections, and we're going to talk about the inspections that you performed. And you said that was on top of investigations. Can you just -- and we'll get into investigations, too, I think, but can you just give the jury a sense of that distinction?

09:20:08 **A** Well, an inspection is you go in and administratively you review everything, from their computer, to their manual recordkeeping system, which would be their prescriptions, their drug stock, their accountability, their biannual inventories. You look at everything. And that pretty much 09:20:40 entailed one agent inspecting pharmacies in his geographic, or other geographics if they're sent there.

And in investigations, I used to carry maybe 30, 40, sometimes 50 cases at a time, and they could be simple things like an error in dispensing, you know, you gave the 09:21:06 wrong drug, the count was wrong to actually drug trafficking, illegal processing. I did a lot of physician cases that resulted in prosecution and conviction, probably 80, 90 plus.

Q Okay. And we'll talk about one or two of those as 09:21:30 well, but do I understand that an investigation sort of ran

the gamut from there was an error in dispensing all the way through there was criminal activity that led to prosecutions? Is that kind of a fair assessment of the spectrum?

09:21:47 **A** No. An error in dispensing, it would have to be a very, very serious error in dispensing that resulted in a death of someone, possibly. Most errors in dispensing -- you know, a lot of times people that were getting controlled substances, the bad people, would say, I didn't get my 120 09:22:13 tablets, I only got a hundred. You know, and they're calling in to question and then they file a complaint, and I would have to go and try to see what the issue was.

Q Okay. So when we're talking about investigations, it sounds like we're talking about criminal activity or 09:22:32 attempted criminal activity?

A Investigations could be administrative and they could be criminal.

Q Okay.

A I handled both ends of it.

09:22:42 **Q** How many -- just talking a bit more about the field agent position. How many field agents were there positioned across the State of Ohio when you were there? And let's take it from say 2005 to 2012 time frame.

Do you recall?

09:23:03 **A** Nowhere near what they have now. I think we had,

like, 16 agents and maybe seven specialists. Those are pharmacists. The specialists are licensed pharmacists that are agent specialists with the Board of Pharmacy, and the agents like myself, a field agent, usually were law enforcement background. So 16 and seven or eight.

09:23:31

Q Yeah. Yeah. And were they sort of divided up by territory in the state?

I understand you were in the northeast part of the state; is that right?

09:23:45

A Yes. There was -- like, I was in Youngstown. There was one up in Geauga County, there was two in Cleveland, one in Akron, you know, spread out.

Q Did your responsibilities or coverage area include Trumbull County?

09:24:07

A Yes.

Q Did it include Lake County?

A No, but I was sent up there a number of times.

Q So there were times there might be an investigation where you would pitch in and head to other areas, territories?

09:24:22

A Yeah. I was pretty much the most senior field agent, especially toward the end of my career, and my field supervisor and my supervisor in Columbus would send me to different geographics to lend a hand.

09:24:42

Q It sounds like your days and weeks were largely filled

with either inspections or investigations or pitching in on investigations.

Was there other substantive worked that occupied your time as a field agent?

09:25:01 **A** Yes. Answering the phone. I would probably have 30 phone calls waiting for me. You got to understand, I had four counties myself for regulatory and investigative responsibility, four counties. You can just imagine how many licensed facilities are in four counties and how many 09:25:24 street crimes or pharmaceutical crimes were occurring. I was pretty busy.

Q And I guess most of this was in the days before cell phones; right? So you'd come back to the office and have a stack of messages or. . .

09:25:38 **A** Well, even when I had cell phones, I didn't really give that number out except for maybe a supervisor of a chain or someone that I needed to talk to. If I would have gave that phone out it would have never stopped. It was always on my recorder in my office.

09:25:57 **Q** Understood.

We've talked a bit about licensing. Did the Board of Pharmacy license prescribers?

A Yes. There were prescribers that were being licensed by the Board of Pharmacy.

09:26:12 **Q** I think you mentioned that a fair amount of your time

was spent doing investigations. That included investigations of physicians?

A Yes. I probably did more than any field agent during my time with the board, 80, 90 plus.

09:26:34 **Q** And you also -- I'm sorry. I didn't mean to interrupt. You said 80 or 90 plus?

A Yes, investigations where I wrote probably the majority of the investigative reports and search warrants that resulted in criminal prosecution and convictions.

09:26:52 **Q** I want to -- I want to switch topics a bit, and I want to focus on pharmacists and your interactions with pharmacists. And to start off on that, I want to ask you about a concept that we've heard about here in court, and that is the pharmacists' corresponding responsibility.

09:27:15 Are you familiar with that?

A Sure. That's in 4729-5 of the manner of issuance. They have a corresponding responsibility to a physician.

Q And if you'll bear with me, you just -- you just referenced a provision of the code that I want to -- that I

09:27:38 want to pull up, but I didn't do a good job of putting it into my outline, so I'm going to see if we can. . . and this will be our first test of whether you can see the document that I'm putting up.

Is that something you can see, sir?

09:27:54 **A** Right, and I pretty much guessed it except for the

last -21. That's it.

Q I was going to say, you impressed us all. This is Tab 2 in your binder if you'd like to look at the hard copy. Okay?

09:28:10 **A** Right. Yeah. That would be here.

I have it.

Q Terrific. So you have correctly identified the provision in the Ohio Administrative Code that deals with the corresponding responsibility, and I just want to spend a

09:28:27 moment looking at the language here. So I'm going to blow up on my screen so folks can see better section A of Ohio Administrative Code 4729-5-21.

Do you see that okay, sir?

A I see it very clear.

09:28:46 **Q** Okay. It reads, a prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice.

Do you see that?

09:29:04 **A** Yes, I do.

Q And just in this provision, does that describe the responsibilities and the obligations of the prescriber?

A Yes, it does. I referred to this many times in my investigations.

09:29:20 **Q** Okay. The second sentence there reads, the

responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

Right?

09:29:39 **A** That is correct.

Q And that provision, just to be clear, that describes the obligations and responsibilities of the pharmacist; right?

A Yes.

09:29:50 **Q** Okay. I want to focus, if we could, then, on the last sentence. It says, an order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription, and the person knowingly dispensing such a purported prescription, as well as the

09:30:16 person having issued it, shall be subject to the penalties of the law.

Do you see that?

A Yes, I do.

Q And based on your 25 years enforcing the pharmacy laws

09:30:34 in Ohio, what does the word "knowingly" mean, when it says knowingly dispensing?

MR. WEINBERGER: Objection.

THE COURT: Let's go on the headphones a minute.

09:31:00 (Proceedings at sidebar.)

THE COURT: All right. Mr. Swanson, are you asking this witness how he interpreted the law when he initiated an investigation or a prosecution? Is that what -- is that what you're trying to get at?

09:31:29 MR. SWANSON: Yeah. That's absolutely right, Your Honor.

He spent 25 years making decisions about investigations to pursue against pharmacy -- against pharmacists based on a violation of this code, and so I

09:31:40 think we're entitled to know what his view was of when he would make that decision or when he would recommend --

THE COURT: Well, that's a different question. If you want to ask him --

MR. SWANSON: His understanding.

09:31:53 THE COURT: If you want to ask him what kind of evidence was he looking for when he opened an investigation, that's -- that's a fair question, but that's not asking him to interpret the law, that's asking him how he did his job, and I'll allow that.

09:32:08 MR. SWANSON: Sure.

THE COURT: So if you rephase it in that way, I'll permit it.

MR. DELINSKY: Your Honor --

MR. SWANSON: Thank you.

09:32:12 MR. DELINSKY: Your Honor, before we leave,

Eric Delinsky on behalf of CVS.

THE COURT: Okay.

MR. DELINSKY: I just want to assert and sort of defend the wording as currently worded. We received extensive factor system from Joe Rannazzisi about red flags, what they are, how they should be handled, how they fit into the four corners of the federal analogue to this statute, and we made a lot of the same objections calling for a legal conclusion, and we were overruled. And the limitation Your Honor put on is the exact limitation that Mr. Swanson led with, which is his experience at the agency and --

THE COURT: Well --

MR. SWANSON: That's why I asked it that way, Your Honor.

THE COURT: Well, that would be a different question. I think -- I think it's fair to ask him how he understood the Ohio Board of Pharmacy to interpret that or construe it in his direction. It's the same way, you know, I allowed Mr. Rannazzisi to testify about what his understanding of what DEA did.

MR. SWANSON: Sure. I can reword it.

THE COURT: All right. So you -- that's a slightly different question.

MR. SWANSON: Yeah.

THE COURT: But it's -- I think they're both

permissible.

MR. SWANSON: Okay. Thank you.

(In open court at 9:33 a.m.)

BY MR. SWANSON:

09:33:37 **Q** Mr. Pavlich, I want to ask you a slightly different question, but again, focusing on this -- on this concept of knowingly dispensing.

Based on your 25 years at the Ohio Board of Pharmacy, what was your understanding of how the Board of Pharmacy

09:33:54 understood and interpreted that word in making decisions about whether to pursue investigations, the word "knowingly"?

A Well, it's one of the culpable mental states, purposely, knowingly, recklessly, negligently.

09:34:15 I could easily explain this highlighted section that you're talking about in this way: If a dentist writes a controlled substance for -- an amphetamine for weight loss and hands it to a patient and that patient takes that prescription to a pharmacy, and the pharmacist sees it's a

09:34:39 dentist and it's an amphetamine, and especially if it's for weight loss, and they dispense it, both parties are wrong criminally and administratively based on knowingly dispensing and prescribing.

Q So you talked about -- and I want to make sure this

09:35:01 was the Board of Pharmacy's understanding. You talked

about -- you talked about different states of mind and you mentioned purposefully and knowingly.

Can you help me understand how the Board of Pharmacy -- were those high standards of culpability -- or of mens rea --

MR. WEINBERGER: Objection.

BY MR. SWANSON:

Q -- mental state? According to the Board of Pharmacy.

A Answer?

Q Yes, please.

THE COURT: Well. . .

MR. SWANSON: Oh, I'm sorry.

THE COURT: I think it's a compound question. If you can break it down, I think it may be easier.

MR. SWANSON: Sure.

BY MR. SWANSON:

Q According to the -- your understanding of the Board of Pharmacy, was the knowingly standard a pretty high requirement of an individual's mental state?

MR. WEINBERGER: Objection.

THE COURT: Overruled.

THE WITNESS: Knowingly is the second highest requirement.

BY MR. SWANSON:

Q So just under purposefully?

MR. WEINBERGER: Objection.

THE WITNESS: Just under you purposefully.

MR. WEINBERGER: Objection.

THE COURT: Overruled.

09:36:10 BY MR. SWANSON:

Q I want to look at the -- at section B now of the code that we were just looking at and ask you some questions about that. I don't want to highlight it. I want to blow it up.

09:36:33 Okay. Focus now on section B of the code here, sir. As a -- as a former agent of the Board of Pharmacy, does this section B -- is it your understanding this outlines the obligations of a pharmacist in dispensing medications?

A To the best of my knowledge, yes.

09:36:57 **Q** So, you know, the jury and we can all read it, I wanted to ask you about a couple of these, one or two of these obligations.

The second one says that a pharmacist, when dispensing a prescription, must perform prospective drug utilization

09:37:17 review pursuant to a section of the code.

Do you see that?

A Yes.

Q Can you tell us what prospective drug utilization review is?

09:37:29 **A** Simply a pharmacist will look at a patient's profile

of all medications dispensed in the profile on the computer screen and determine if there is something contraindicated for that patient, or more simply, they're getting their controlled substance or their other medication too early, or they're seeing another doctor for a similar drug. These --

This is the drug utilization review, that a pharmacist uses their expertise to determine to continue dispensing what is now in front of them being requested to be dispensed.

09:38:14 **Q** Okay. The -- I want to see. If I pull down a document, can we get the -- does the witness come back up to the. . .

I'm sorry, sir. There's just some technical details we're dealing with on our end. That's why there's a pause here.

A Okay.

Q Well, let me continue and see if we can -- there you go. You were in a little box. We wanted you back in the big box, so welcome back.

09:38:55 The jurors in this case have heard a lot of testimony about so-called red flags relating to individual prescriptions.

Red flags, is that a term that you're familiar with or that you used in your time at the Ohio Board of Pharmacy?

09:39:13 **A** I'm familiar with the term. Whether I used it or not,

I don't think it was a common term that I used.

Q The -- well, I guess the concept, and tell me if we're on the same page, was that a patient might present with a prescription and there might be questions, or concerns about the prescription that the pharmacist should try to address in ensuring that the prescription was written for a legitimate medical purpose.

You understand that concept?

A I understand.

09:39:48 **Q** Okay. So whether -- you might call it a red flag, you might call it a concern, sort of talking about the same thing?

A Yes.

Q And if a prescription, like the one I described, is 09:40:05 presented to a pharmacist and the pharmacist has concerns or thinks it's a red flag, the pharmacist should do something to try to address those concerns or that red flag.

Is that fair?

A Yes, that's fair.

09:40:19 **Q** Can you give me -- was -- when you were at the Board of Pharmacy, was there, like, a list of concerns or a list of red flags that you provided to pharmacists to make sure that they were checking every box on red flags or not?

Do you recall?

09:40:38 **A** There was the Drug Laws of Ohio law book. In that law

book, there was a lot of so-called red flags, legitimate medical purpose, issues to address. Too numerous for me to think about at this time in my life. But I would bring up things to the attention of a pharmacist if I saw something that needed to be addressed. A prescription that looked like it was altered from maybe 10 tablets, someone put a 0. That's an example.

Q Okay. So an altered or a fraudulent prescription, that's obviously a red flag or a concern that needs to be addressed; is that -- that's fair; right?

A That's one of the many.

Q Okay. Let me give you another example that the jurors have heard testimony in this case, that if a prescription comes from a prescriber who lives -- or who's -- who re -- who's office is more than 25 miles from where the patient resides, that's a red flag; in every instance it needs to be resolved by the pharmacist.

Was that your experience, sir, when you were at the Board of Pharmacy, that there was a hardline of 25 miles?

MR. WEINBERGER: Objection. Mischaracterization of prior testimony.

THE COURT: Yeah, I -- sustained.

BY MR. SWANSON:

Q Let me just ask you more generally, sir.

Was there -- when we're talking about distance between

a physician and a patient, where the patient lives, was there some kind of hardline that you enforced at the Ohio Board of Pharmacy that said if a doctor is more than X miles away, that's a red flag that needs to be resolved?

09:42:26 MR. WEINBERGER: Objection.

BY MR. SWANSON:

Q Was that something you did?

MR. WEINBERGER: There's no foundation laid, Your Honor.

09:42:30 THE COURT: Well, I --- overruled. He can ask the question.

BY MR. SWANSON:

Q Go ahead and answer, sir.

A There was -- there was no specific mileage per se, but 09:42:47 if I saw -- for an example, one of the last major cases I worked, there was a doctor in Geauga County. None of the pharmacies near him were really filling his scripts. The patients were all driving 35 minutes south to a pharmacy in Trumbull County, an independent pharmacy, mind you, and they 09:43:11 were filling their scripts there. That is an example of beyond the limit.

Now, if I was in a pharmacy and I saw one prescription from a patient -- from a doctor in Cleveland and it was in a pharmacy in Trumbull County, you know, it might have been a 09:43:34 specialist, they might have gone up there to see this doctor

for something, one, two, three, is not a major concern. But when you see a lot, a real lot, from a -- one particular doctor in particular, then red flags, as you say, go up.

Q And I think you're talking about Dr. Franklin and Overholt's Pharmacy; is that right?

A Yes. I wrote the investigative report and the search warrant --

Q Yep.

A -- and conducted that investigation.

Q Yeah, and I want to talk to you more about that in a little bit, but it's good that that's fresh in your mind because we're going to return to that.

Let me just ask you more generally. When you were an agent at the Board of Pharmacy, did you expect that pharmacists would exercise professional judgment in filling a prescription?

A I required it.

Q More generally, working in Trumbull County where there are some smaller towns, smaller communities, did, in your experience, did you find that pharmacists and the pharmacies there would often get to know the patients who came in, develop relationships with them?

A Yes.

Q Would the pharmacists tend to know the physicians and the practices who were working in the community?

A Yes. Most of my information came from pharmacists.

Q And what do you mean by that, most of your information came from pharmacists?

A Where they had, as you say, red flags about something, concerns about a patient, they would call me and I would respond.

Q So when you're talking about getting calls from pharmacists alerting you to maybe questionable physicians or practices, does that include calls from pharmacists at Walgreens?

A Oh, absolutely.

Q Does that include calls from pharmacists at CVS?

A Absolutely.

Q Does that include calls from pharmacists at Walmart?

A Absolutely.

Q So were those three pharmacies and the pharmacists who worked there, in your experience, were trying to reach out to you to help you in your job of going after physicians who were maybe didn't have the best practices?

A I received a lot of help from pharmacists at those three chains, at numerous chains. I always received total cooperation.

Q I want to talk to you a little bit about documentation and the documentation that a pharmacist might do.

Are there certain things that a pharmacist, in your

experience, would be expected to document when filling out a prescription, like how many pills are being dispensed, or whether a patient has allergies, that sort of thing?

A Yes.

09:46:53 **Q** And you would expect that for those things that a pharmacist would -- would document that those -- that he or she had evaluated, had done the right thing with the number and had alerted the patient to whether there were allergies or drug interactions?

09:47:11 **A** Yes. My quote to pharmacists was, your prescription is your Bible. If you got something you want to bring to my attention regarding a prescription, write it on the prescription. When they dispense it, they put their manual initials. I know who dispensed that prescription.

09:47:30 **Q** Got it. So to go back to an example you gave before, a patient -- or a pharmacist might write, I dispensed a hundred pills. Then if the patient came to you and said, hey, I only got 50 pills, you could take that to the pharmacist and the pharmacist could say, no, I wrote right here on the prescription that was a hundred pills.

09:47:49 Is that an example of what you're talking about?

A Yes. That -- that's a -- an example of what they document. Not saying that, you know, we're all human. We could miscount, but in the majority of times I found I would trust the pharmacist's recordkeeping more so than a person

09:48:13

calling me up saying I didn't get 20 of my controlled substance pills. You'd have to have a lot better proof than that for me.

Q Okay. And to go back to another example that you gave to me, you said, well, if there was a -- or a pharmacy in Trumbull County, and you saw that there was a prescription that had been filled by a specialist in Cleveland, in your view as an agent for the Board of Pharmacy, that to you wouldn't constitute a red flag if it was just, you know, one or two scripts.

Is that fair?

MR. WEINBERGER: Objection. Your Honor --

THE COURT: That's sustained.

MR. SWANSON: Well, I'm trying to ask you about, do you remember giving me the example of a pharmacist in Trumbull that's filled a prescription that came from the Cleveland Clinic from a specialist there?

MR. WEINBERGER: Objection.

THE WITNESS: I did.

THE COURT: Well, overruled.

BY MR. SWANSON:

Q And in your view, when you gave me that example, is that example -- an example of what you consider to be a red flag or not a red flag?

A Not a red flag for a limited number.

Q Okay. And so for that limited number, you wouldn't have an expectation -- well, I don't want to put words in your mouth.

For those prescriptions at the pharmacy -- at the pharmacy, would you expect that there would be documentation to -- on that regarding the specialist or where it came from or whether there was a conversation with the physician?

A I might bring it up to the attention of the pharmacist and they would usually expand upon it because they would have firsthand knowledge, but like I say, unless it was an expensive repetitive quantity, a number of prescriptions, wasn't really a red flag.

Q Was there any -- was there any legal requirement in the Ohio code that required a pharmacist to document when he or she had resolved a red flag in a prescription, legal requirement?

A I'm not certain on -- I know they have the corresponding responsibility and they have to document what they dispense to an accurate accounting for what's on the prescription, or if it's less, to document that. Where it is in the code, it's been a long time.

Q Okay. But I -- and I appreciate that, and if your memory doesn't call everything up, that's understandable to everybody here, but I just want to make sure when you were just talking about documentation, were you talking about

documenting, for example, the number of pills that were dispensed?

A Yeah. That would be -- before computers, it was manually generated on the prescription. After computers came out, there was a label affixed, and it would show a hundred prescriptions prescribed -- or hundred tablets prescribed, a hundred tablets dispensed on the black label that's affixed to the prescription, which would be also on the patient's bottle that was dispensed to the patient, and in the accountability records, at the end of the day, that they would generate, and I could refer to all these recordkeeping methods to make an accurate determination if I didn't have to do an audit.

Q But to return, again, to your example of the Cleveland Clinic and the pharmacy in Trumbull, I think -- and you can correct me if I misheard you, but I think what you said is you might go in and the pharmacist would know the prescription or know the patient and so could explain to you why that prescription had been filled.

Did I accurately capture what you were saying?

A Yeah. The pharmacist would know better than me.

Q Okay. I want to turn now, if I could, sir, to something that we touched on briefly before, and that's inspections of pharmacies. Okay?

A Go ahead.

Q And -- thanks. And one of the -- I think this is clear, but I just need to make sure we have a record.

During your tenure at the Board of Pharmacy, you conducted investigations of chain pharmacies in Trumbull County; right?

A I did.

Q And I misspoke, and thankfully I have a team here helping me. I said investigations. I meant to say inspections. So let me reask --

A I did that too.

Q Is that how you --

A I did that too.

Q Okay. So let me ask you, you conducted inspections of all of -- of pharmacies in Trumbull County; right?

A Yes.

Q That includes inspections of the chain pharmacies in this case, Walgreens, Walmart, and CVS?

A Something happened.

Q Can you -- can you hear me?

A All right. You're back.

Q Okay.

A Yeah, that included chained pharmacies, too.

It paused on me.

Q Do you know, did you conduct inspections of every Walgreens pharmacy in Trumbull County over the course of

your career?

A Yes. I would say at least once.

Q Maybe more; right?

A Oh, probably a lot more.

09:53:52 **Q** Okay.

A But at least one.

Q And is that the same answer for CVS?

A The same for all chains and all independents. I had a requirement, and I would look at the geographic and I would

09:54:05 see I hadn't been in there a year, and I would do my best to go there and look things over.

Q And I take it from your answer that these inspections that we're talking about, they were conducted on-site at the pharmacy itself?

09:54:20 **A** Yes. I would be physically there.

Q How long would these inspections typically last?

A I was pretty thorough. I would say mine averaged 3 hours, minimum 2 hours. I mean, there might be something I was just in the pharmacy to retrieve a prescription or

09:54:46 look at something not that relevant to an investigation so it would be short. But if I was doing a full inspection in a pharmacy, I would say about 3 hours, 3 and a half.

Q I'm sorry, 2 and a half to 3 hours on average?

A Yeah, I'm -- a full inspection.

09:55:07 **Q** Was one of the purposes of your inspections to ensure

that the pharmacy was complying with the rules around dispensing of prescription medications like opioids?

A That was one of the reasons.

Q Was one of the purposes to ensure that pharmacies were adhering to the code requirements with respect to effective controls and procedures to detect and prevent theft and diversion?

MR. WEINBERGER: Your Honor --

THE COURT: This -- I'm going to sustain -- that's too much -- too leading, Mr. Swanson.

MR. SWANSON: Okay.

BY MR. SWANSON:

Q Can you tell us -- you've mentioned one of the purposes of your inspection. Can you tell us some of the other purposes of the -- of your inspections of pharmacies in Trumbull County?

A There was many purposes. Regulatory compliance, recordkeeping, accountability, get to know the pharmacists who are working there, find out what's going on in their geographic.

I mean, inspections involve hands-on learning what only you can learn by speaking to people that are there all the time. They're your -- as -- as a street cop would tell you, they're your informants. They're the ones that supply you with knowledge that you wouldn't have if they didn't

tell you.

Q And by they, you're talking about the pharmacists and the staff at the pharmacies that you were inspecting?

A Primarily the pharmacists.

09:56:58 **Q** During your inspections, would you look at whether the pharmacists were conducting drug utilization reviews, something we just talked about?

A Yes, I would. They would sign off on those.

Q I think you mentioned this before, but I want to make

09:57:14 sure I heard you correctly.

During these inspections, would you look at the pharmacies' dispensing systems that the pharmacists used?

A Defensing [sic] system?

Q I'm sorry, dispensing. The computers.

09:57:30 **A** Oh, I thought you said defensing.

Yes, I would look at their dispensing accountability.

Q And through your inspections of Walgreens, Walmart, and CVS, did you become generally familiar with the computer systems at those -- that those companies' pharmacies used?

09:57:46 **A** Well, I was far from being an expert, but I had a working knowledge.

Q Did you have the knowledge that you felt you needed as a Board of Pharmacy agent to conduct a thorough inspection?

MR. WEINBERGER: Objection.

09:57:59 THE COURT: Overruled.

THE WITNESS: I did.

BY MR. SWANSON:

Q Do you know, does the Board of Pharmacy have to approve each pharmacy's computer system that they use for dispensing?

09:58:13

A They did.

Q When you went in and did these inspections, would you look at the actual physical prescriptions that the pharmacy had filled?

A I always did.

09:58:32

Q And when you did that, did you have access -- and I'm talking about at Walgreens, Walmart, CVS -- when you did that, did you have -- did you have access to the entire file of prescriptions, or did you just look at one or two?

A Oh, I never looked at one or two. I had access to, I think as the rules require, three years of accountability, but most pharmacies maintained at least, I believe it was 7 years because of IRS requirements. But three years, I think, was in the law at the state Board of Pharmacy law book.

09:58:53

09:59:19

Q So when you went in to -- my client is Walgreens.

When you went into a Walgreens pharmacy for an inspection, you had access to three years of prescriptions.

Is that true?

A That is true.

09:59:33

Q And I -- did you consider yourself to be a pretty thorough investigator?

A I thought I was very thorough.

Q During your inspections, would you look at the actual patients who were coming in with prescriptions to have filled?

A Well, if they were standing there in the pharmacy I did.

Q Okay.

A But if they weren't there, I might ask a question of the pharmacist. If -- if this patient is getting an exorbitant amount of medication -- and I can think of two right away -- I would say, what's this guy look like? You know, how is this guy functioning based on what you're dispensing to him? And I'd look for an answer from these pharmacists and see if I got a little stuttering, to say the least.

Q Which might raise your suspicion?

A No. I had a pharmacist that used to stutter every time he lied to me, so, yeah, that raised my suspicions.

Q The police officer in you would come out in those situations, I take it?

A Yes, it did.

Q And for these inspections that we're talking about, were they something where you'd call up the pharmacy and

say, hey, I'm going to be there in a couple weeks, or would you just show up?

How did that work?

A Surprise, I'm here. I never called, unless I had called and said I need a specific profile printed on Jimmy Bob Smith or Joey Davis and they would have it ready, and I said, I'll pick it up in an hour or two, and they would provide it for me and I would go. But that really wasn't an inspection. I might leave an inspection sheet that says I obtained a profile, but I never called when I did a full inspection. I just arrived.

Q I take it you wanted to be sure that the pharmacies you were inspecting couldn't prepare for your visit. You wanted to see how they were actually functioning in real time?

A That's for sure.

Q And if you were doing an inspection and you found areas where the pharmacy or the pharmacists were falling short, would you let them know?

A I would let them know orally or written on an inspection sheet. If I felt -- you know, pharmacists are very intelligent and they do a great job and they got a lot of things to take care of, including all the insurance, and, you know, if they didn't put their initial, on, you know, a script but did the majority, or they didn't sign off on a

log but did the majority signing off, or something like that, misfiled a controlled substance prescription with a dangerous drug prescription, I'm not going to write them up and send a report to Columbus that said, oh, my, look at this, I caught them with three prescriptions misfiled.

It was usually written up for something that I wanted to directly bring it to their attention and you better cease and desist. I was pretty -- pharmacists were cooperative with me, and I was cooperative with them to the point of working well together.

Q Was it important to you, in doing these inspections, to ensure that pharmacists and pharmacies that you inspected were complying with the Board of Pharmacy's rules and regulations?

A Yes. I mean, if there was something that needed attention, it was written and documented it needed attention.

Q And if you found evidence of diversion or suspected diversion, I take it that's something that you would alert the pharmacy and your superiors to?

A Yes, and I will add, the majority of the time, chain pharmacists or chain pharmacies, pretty much all of them, were the most compliant. The least compliant was always I would find in independent stores. Not saying that chains didn't have some bad apples in there and I went after them,

but not specifically regulatorily. They were pretty uniformed as to how they documented and did things, pretty much all of them.

Q And by chain pharmacies, just so my record is clear, Walgreens, Walmart, and CVS, in your view, in your experience, were very compliant with the laws of Ohio?

A Well, in my opinion -- I'll say it this way. I was with the Board of Pharmacy for 25 years. I do not recall one chain pharmacy that had a revocation of the license for that chain pharmacy that I was involved in. Not one. But I could tell you there were numerous independent ones.

Q And what leads --

A So --

Q I didn't mean to interrupt.

A No. So, I think that explains it.

Q I want to get into a -- into a specific report, just to give the jury a sense for the work that did you.

But let me ask you first, we've talked about some of the reasons that you would do inspections and some of the things that you would look for. Was that, in your view, consistent across the other agents with the Board of Pharmacy that you interacted with?

A Well, it was required, but not everybody did everything the same way. Some -- some agents weren't as thorough, if I may use the word. Some agents weren't as

capable at doing large investigations as other agents. It varied, but we were required to be thorough. Doesn't mean everybody was.

Q If you could turn in your folder, sir, to Tab No. 1. I want to ask you about what I believe to be one of the inspection reports that you completed of a Walgreens.

A Yes, that's my signature.

Q Okay. So I want to make sure we're looking at the same thing. I've called up for the jury here an inspection report, and just to orient us here, I'm going to blow up briefly on the bottom.

You can see this is signed and dated August 9th of 2006; right?

A That is correct. That's my signature next to it.

Q Okay. Right -- right here (indicating).

A Right there.

Q That's you. Okay.

Now, I want to ask you, at the top there, you give some details about the inspection. It shows that you arrived at the Walgreens at 11:15 and you were out at 2:45. So that's about 2 and a half hours, which is consistent with what you said before?

A 1:45. Not 2:45.

Q Oh, I gave you an hour. What I meant to say is 1:45 equals 2 and a half hours?

A Yeah. And that's pretty much what I said, 2 and a half, 3 hours.

Q Correct. And you can see, there's a line there for responsible person, and it shows a pharmacist there named Brian Joyce.

Do you remember a Brian Joyce who was a pharmacist at Walgreens?

A I remember Brian Joyce very well. He was an excellent pharmacist.

Q Okay. And the jury's actually heard him testify in this case at this -- in this trial.

When you say he was an excellent pharmacist, what made him an excellent pharmacist?

A I knew Brian Joyce as far back as when I was with the Youngstown Police Department and he worked at an independent pharmacy. Through his career with Walgreens, when he became a supervisor eventually, I never, ever, that I recall, have a major issue with Mr. Joyce, ever. He was always responsible. He was always compliant. He always called me if he had issues or concerns. He was excellent.

Q All right. Was he a guy who would tolerate pharmacists or pharm techs who weren't responsible?

A Not that I'm aware of, no.

Q Was he someone who would call you if he suspected there were doctors who weren't doing things the right way?

A Yes.

MR. WEINBERGER: Objection, Your Honor. Objection.

THE COURT: That's sustained.

BY MR. SWANSON:

Q Did you ever receive calls from Mr. Joyce?

A Many.

Q And what are some of the reasons Mr. Joyce would call you?

A Doctor shopping. This is before the OARRS electronic database system. He would call me and say, hey, I was talking to Jim up at Rite Aid and they said this patient that I got was also in their store with a different doctor getting the same controlled substance. That's an example. Or someone came in with an altered prescription. Brian called me all the time. I knew him very well.

Q Was -- was Mr. Joyce the kind of pharmacist who would put profits over safety at his pharmacies?

MR. WEINBERGER: Objection.

THE WITNESS: No.

THE COURT: Sustained. The jury is to disregard the question and the answer.

BY MR. SWANSON:

Q During your inspections of pharmacies, would you talk to pharmacists and their staff and their technicians?

A Yes.

Q Would you discuss the policies and procedures that the pharmacies had in place?

A Yes.

10:11:01 **Q** And you recall you did that at Walgreens?

A I was there 2 and a half hours, I would say yes.

Q I want to ask you, if I can, sort of go through this report piece by piece. On the left-hand side there is -- there are a number of, I don't know, call them issues or -- 10:11:27 well, I'll call them issues because I can't think of another word, but maybe you can tell me what these 37 numbered issues are.

Call them what you want to, but can you tell us what you -- what I'm showing there?

10:11:42 **A** These 37 items are standards to conduct an inspection, starting off with licensing. Do they have the federal? Do they have the state license? Do they have their personal pharmacist license? Today, do the technicians have their licenses? And so on and so forth all the ways down to 10:12:08 counseling. Are they providing counselling to the patients at the time when the prescription is being dispensed? Is there a recordkeeping file available that documents this? Guidelines. Not that you have to check each block, it's -- it's a guide.

10:12:30 **Q** Can I just ask you about a few that I had questions

about, if you can help clarify them for me.

You see Number 6 there, there's an item, security?

A Yes.

Q What does that mean? What were you checking when you have that item for security?

10:12:46

A Well, I was making certain that the pharmacy was barricaded in the respect that if a pharmacist left the store and the store was still open, is it secured, either by electronic means -- an alarm system -- or a physical barricade -- sealing it off. Were all the drugs stock within the barricade? Was all the recordkeeping secured so no one could, for an example, a front-end clerk go into the backroom and look through various RX files and see what Jimmy Bob Smith was setting security.

10:13:07

10:13:34

Q Did security looking at the security of the computer systems that the pharmacy might have in place?

A I wasn't really adept at computers. Security would mean with the computers that were -- they were maintained within the environment of the pharmacy. There was no access to it outside. As far as it blocking down and everything else, beyond my capabilities.

10:14:01

Q Okay. And you see look at cleanliness. What about Number 11 here, improper dispensing. What did that -- what did that item refer to?

A Pretty much what it says, were there prescriptions on

10:14:28

file for an example that shows 10 prescriptions were prescribed by the doctor in blue ink, and then I see a black circle next to it showing a hundred and they dispensed a hundred.

10:14:43 Now, to me, that would say you're not paying attention and you dispensed a hundred instead of 10 as written by the doctor. I mean, that's a -- a very broad example of something, but anything that's improperly dispensed would come under that category.

10:15:01 **Q** And I guess we talked a bit before about a pharmacist's corresponding responsibility, and we had some questions and answers about that. Is the -- is that improper dispensing item, is that where you would evaluate whether the pharmacists were exercising their corresponding

10:15:17 responsibility?

A Yeah, that would be one of the categories.

Q And if a pharmacist at a Walgreens, Walmart, CVS were failing to exercise their corresponding responsibility, would you note that in the inspection report?

10:15:31 **A** I would.

Q Again, I don't want to look at all of these, but there were some I had -- I had questions on.

Number 20, improper prescriptions. Can you tell us what that means?

10:15:48 **A** It's similar to what Number 11 is, improper

dispensing. Improper prescriptions could also be when a telephone prescription is being called into the pharmacy from a doctor's office and they're not using the proper standards to document that, like for an example. . . they're not documenting the full name of the person calling in the prescription, they're just putting Jimmy Bob, but not Jimmy Bob Smith, and that's required. So that would be an improper RX. You're not documenting the full requirements of that prescription telephoned into your pharmacy.

10:16:40 **Q** All right. Just one or two more that I wanted to ask you about.

Number 26 here, RX or prescription files. What was that item that you would look at when you did these inspections?

10:16:55 **A** I would look at their manual documentation file. There would be, obviously, Schedule II controlled substances were filed separate. Schedule III, IV, and V were in a separate files, the actual prescriptions, and then the legend route, which are still prescriptions but they're not

10:17:25 controlled would be in a third file, and those are the RX files that I would manually look at every time I did a full inspection.

Q Okay. And you've talked about this before. It sounds as though this were -- this was a pretty important part of

10:17:42 the inspections you'd conduct?

A It was probably one of the most important.

Q And I was going to ask, I mean, if you're -- if 2 and a half, 3 hours was sort of your standard for an inspection, how long, in general, if you can recall, would you spend going through the prescription files and looking at individual prescriptions?

A Well, I'd spend a long time. I would spend at least a half an hour on each controlled substance. So half an hour on the II's and half an hour on the III, IV, and V prescriptions, and not quite as long on the not quite as long on the regular prescription drugs.

It all depended on what their volume was in the pharmacies. I mean, some pharmacies would do 50 scripts a day, some would do 500 scripts a day, so I would spend a lot more time in the one that did 500 than the one that did 50.

Q And in those hour, hour and a half you were looking at actual physical prescriptions, if you had questions, was a pharmacist there to answer questions for you?

A Yes, he was, or she was.

Q And if that pharmacy were maintaining prescription files that didn't comply with the state or federal regulations, is that something you'd write up?

A Oh, yeah, yes, I would.

Q All right. Let me ask you, just below that list that we just looked at there's a box there that says pink sheet

issued for numbers, and then it leaves a line where you can put in numbers.

Can you tell us what that is?

A A pink sheet is, in my day, a manually required reply to issues that I note by numbers. For an example, Number 1, licensing, I would put Number 1 in the line next to it and above that, within the body of the inspection report, I would have Number 1, couldn't find terminal distributor license, and that would be a pink sheet.

10:20:18 Then I would give them a copy of the pink sheet and their regular inspection sheet, and the pink sheet would have to be sent to Columbus within 20 days or something like that with a reply stating we do have a terminal distributor's license, here's a copy of it, it was misfiled

10:20:42 or whatever, but they have to write a written reply and send it to Columbus because I had special intentions for them to show me an answer for that.

Q It looks like, for the -- for the prescription that we're looking at -- and I should have said, just for the

10:21:02 record, if you'll excuse me, Mr. Pavlich, this is Defendants' Exhibit WAG-MDL-1110A. It looks like for the prescription -- or for the inspection report we're looking at there was no pink sheet issued.

Is that fair?

10:21:24 **A** It's not marked on the first page. Let me look

through this.

Q Sure.

A No, there was no pink sheet issued. If you go through it and you look at Page 4, again, it's not a pink sheet, it's kind of a note for the RPh. I make a note about first and last name of the agent, which was, for -- as an example, what I said was, for that category that you talked about, I note RPh, the receiving of prescriptions via telephone requires the RPh document first and last name of the agent, nurse calling in, the prescriber RX, see 4729-5-30 ORC.

So, again, that was an example of something that I saw, and it wasn't extensive, it wasn't to the point that I needed a written reply. I was bringing it to the attention of the three pharmacists and the intern working in that store and saying, let's do a little better job here.

Q Okay. And I think I caught up to you. You were saying on the fourth page there was a note of something that you saw that wasn't in perfect compliance, you wanted to bring it to the attention of the pharmacy but it didn't rise to the level of a pink sheet.

Is that fair?

A That's fair, and it probably was, you know, not extensive or I would have pink sheet.

Q Okay.

A There was some -- there was some documentation that

needed to be brought to their attention, and I write it down like that because I'm there with -- oh, God, I can't even pronounce his name -- pharmacist that's listed first on that inspection report, but I want to make sure that the other pharmacists that aren't there see this on the inspection report and address it when they're in the pharmacy.

10:23:30

Q So that's an -- I don't know this person, it looks like Enouha? Is that the pharmacist?

A You got me. He uses the initials EEO.

10:23:48

Q All right.

A I can't pronounce that.

Q Well, let's agree that's the right pronunciation, but that's the person then that you would say, hey, you know, make sure this gets corrected at your pharmacy?

10:23:59

A Yeah. It was brought to their attention and for the attention of the other pharmacists. Not in a written requirement to reply back to me, just pay attention. That's all.

Q Okay. And I want to, if I can, ask you about a couple of these.

10:24:18

You see there on the first page the pharmacy has IntercomPlus software with five patient dispensing computer screens.

Do you see that?

10:24:33

A Yes.

Q And do I understand correctly, that's a reference to the Intercom Plus dispensing system that Walgreens was using?

A Yeah, I believe at that time that's what they had.

10:24:45 **Q** Okay. And by five patient dispensing screens, does that mean they had five different computers that pharmacists or techs could use to enter data?

A Yes.

Q The -- I take it that -- well, was every Walgreens

10:25:11 inspection that you did perfect?

A Nobody's perfect, including me.

Q Okay. Would you sometimes find reason to issue a pink sheet to a Walgreens pharmacy?

A I'm sure I have. You know, for me to recall -- I'm

10:25:37 sure I have. But I wasn't one -- I wasn't one -- I didn't have to show a pharmacist that I'm not a pharmacist, but I sure as heck can figure out what's going on in this pharmacy.

I think my reputation followed me around, and they

10:25:55 knew if I was there, I meant business and I wanted a standard met. And I used to tell pharmacists, whether they were in a chain or they were in an independent store, you have to comply the same as a chain does, the same as an independent does. I don't pull favorites. Everybody got to

10:26:21 do the same thing. If you're not, you got to answer to me

because you're a reflection of me out here in the field.

And I used to put this straight across to them and they -- they understood.

Q Let me ask you if you can recall more generally, what was the expectation if you did have to issue a pink sheet to a pharmacy, what was the expectation that you required from the pharmacy or the pharmacist?

A If I issued a pink sheet?

Q Yes, sir.

A They would have a certain number of days to -- oh, it's right on the inspection sheet. 20 days to reply manually on the back of the pink sheet, forward it to Columbus, and then Columbus would send their reply back to me and I would look at it. And if their reply was this agent doesn't know what he's talking about, he's not even a pharmacist, which I had that said one time, I would go back --

Q Not by Walgreens, I hope.

A -- I would end up back in that pharmacy very shortly after that.

But 99 percent of the time they would say, we're doing our best. We are going to comply. This was an oversight, so on and so forth.

Q Okay. Thank you.

MR. SWANSON: Your Honor, I'm being to move to

a new topic.

THE COURT: Okay. That's fine. I was going to suggest a time for our break.

Ladies and gentlemen, we'll take our mid-morning break, 15 minutes, and then we'll continue with this witness' testimony.

(Jury excused from courtroom.)

(Recess was taken from 10:28 a.m. till 10:48 a.m.)

COURTROOM DEPUTY: All rise.

(Jury returned to courtroom at 10:50 a.m.)

THE COURT: Okay. Please be seated, and Mr. Pavlich, I just want to remind you you're still under oath from before the break.

And, Mr. Swanson, you may proceed.

MR. SWANSON: Thank you, Your Honor.

BY MR. SWANSON:

Q Welcome back, Mr. Pavlich.

Before we broke, we were talking about the inspections that you had performed at Walgreens pharmacies in Trumbull County, and I just have a few follow-up questions on that topic.

Do you recall, sir, in all of the years that you conducted inspections of Walgreens pharmacies in Trumbull County ever having any issues with the systems that Walgreens used to dispense prescription medications, like

opioid medications?

A I don't recall. I don't recall any -- any problems.

Q Is that the same answer for CVS?

A Yeah, I don't recall any with CVS either.

10:51:30 **Q** And same for Walmart, sir?

A And I don't recall any problems with Walmart system either.

Q And did you ever have any issues with the systems that Walgreens used for maintaining records and data?

10:51:49 **A** No.

Q Same answer for CVS?

A Yes.

Q And same answer for Walmart?

A Yes.

10:52:03 **Q** Are you aware of any Walgreens, a pharmacy in Trumbull County, ever being subjected to criminal or a civil investigations due to improper dispensing?

A As I earlier testified, I don't recall any specific chain, any, ever having a revocation of their license for a

10:52:28 criminal for administrative case. I recall pharmacists, but not the chain.

Q Okay. And let me follow up because you've mentioned a couple of times that we have the chain pharmacies like Walgreens and CVS and Walmart, and then you've mentioned

10:52:47 independent pharmacies.

Can you tell us what independent pharmacies are and what's the distinction you're making there?

A Chain pharmacists [sic] is owned by a corporation that, for an example, would have numerous pharmacies, Walgreens, CVS, Walmart, Giant Eagle, numerous.

10:53:08

An independent pharmacy is one that is owned -- it might be set up as a corporation, but by individuals pharmacist or pharmacists with the express purpose of having one store, maybe two, maybe three, but not to the extent of a chain pharmacy. So there was a big difference between the two where pharmacists worked, big difference.

10:53:36

Q I'd like to -- I'd like to pivot now and -- and talk to you a little bit about pharmaceutical diversion in Northeast Ohio. And diversion is the topic that you defined for us earlier today.

10:54:05

If you could turn to Tab 3 of your notebook, I want to ask you about a specific document.

A Okay.

Q I've put up on the screen, it's in your tab, what I've marked as Defendants' MDL 12052, that's the Exhibit Number. It's An Ohio Prescription Substance Abuse Task Force.

10:54:30

Were you aware when you were at the Board of Pharmacy that the governor of Ohio had brought together a task force to look into the issue of prescription drug abuse in the state?

10:54:53

A Well, first of all, I don't remember ever seeing this booklet, and as far as the task force, I worked with Trumbull County Drug Task Force, Mahoning County Drug Task Force, and Columbiana County Drug Task Force, but nothing out of the governor's office that I remember.

Q If you can look, I flipped to Page 9 --

MR. WEINBERGER: Objection, Your Honor.

THE COURT: Well. . .

Let's go on the headphones for a minute.

(Proceedings at sidebar.)

THE COURT: All right. Mr. Swanson, the witness said he doesn't remember anything about this. If there's something on that -- you believe this witness had anything to do with this task force and he's just forgotten and there's something about this page that will prompt his memory? I mean, he's deposed.

MR. SWANSON: Yeah. He wasn't deposed on this. I was just going to ask him, the head of the BOP was on the task force, and so I just wanted to see if he -- if he doesn't know, I'll take it down. But I just wanted to ask, because the head of the BOP was a member of the task force, if it was something he ever discussed. And if not I'll move on.

MR. WEINBERGER: He's already testified he has no knowledge of this document.

THE COURT: Well, I don't -- no. He can show him who -- I mean, who was on it and does -- all right. If you want to ask him -- fine, you can ask him that one question.

10:56:29 MR. SWANSON: That's fine. Yeah. I'll move on if he's not --

THE COURT: Yeah.

(In open court at 10:56 a.m.)

BY MR. SWANSON:

10:56:43 **Q** So, Mr. Pavlich, I've put up from the exhibit here a list of the task force members, and I just wanted to ask you one question.

If you look in the lower right-hand corner, one of the task force members was William Winsley.

10:57:03 Are you familiar with him?

A Yes. He was the executive director of the Board of Pharmacy.

Q Okay.

A He was a pharmacist also.

10:57:12 **Q** Okay. And he was on the task force, but you don't have any recollection of ever seeing this document or discussing it?

A I don't recall ever seeing this document, and as far as him being on this task force, I didn't know about it.

10:57:27 **Q** Okay. Then I'm not --

A That I recall.

Q All right. Then I'm not going to ask you about it.

But I do want to ask you some general questions about -- again, about diversion in Northeast Ohio.

10:57:40 Are you familiar internet pharmacies that existed while you were at the Board of Pharmacy?

A I'm very aware. I did a large investigation on one.

Q Can you tell the members of the jury what an internet pharmacy is when you use that term?

10:58:04 **A** A pharmacy that has a retail setting. In my particular case was an independent pharmacy, and they were receiving electronic data-generated prescriptions over the internet into their pharmacy and then preparing prescription medication and FedEx, UPS, whatever, sending it out to

10:58:36 patients without a face-to-face examination by a physician to a patient, which is one of the requirements -- at least it was when I was working -- for a physician to have a face to face with a patient, not fill out a form and we'll send you prescription drugs. That's an internet prescription.

10:58:58 **Q** Yeah. And I think you said that you conduct -- excuse me -- conducted an investigation into an internet pharmacy in Ohio?

A Yes. It involved a million, and I believe, a quarter prescription doses.

10:59:14 **Q** And million and a quarter, you said?

A Approximately around that number.

Q Where was the -- where was the pharmacy?

A In Mahoning County.

Q And you said that was an independent pharmacy?

10:59:27 **A** Yes. It lost its license and he lost his license, and convicted of felonies.

Q Did you investigate other internet pharmacies while you were a member of the Board of Pharmacy? An agent for the Board of Pharmacy, excuse me.

10:59:41 **A** No. That was the -- that was primarily the only one that I did, and it took a while.

Q Do you recall what year it was that you shut down that pharmacy?

A As a matter of fact, it went right toward the end of

10:59:59 my career, the administrative and criminal conclusion. So that would have been to -- the end of 2011 -- the fall of 2011, and I believe he pled in January of 2012 or February of 2012.

Q Another topic that I think we at least mentioned, but

11:00:28 if not we will now, were pill mills in Ohio.

Are you familiar with pill mills and what they are?

A I am.

Q Can you tell us, how do you describe or define a pill mill?

11:00:46 **A** The excessive prescribing, dispensing of controlled

and/or legend prescription medication with no manner of issuance and legitimate medical purpose as a standard.

Q Was there a time when you were an agent for the Board of Pharmacy that there existed doctors who could set up an office and see patients, write prescriptions for the patients, and then dispense those prescriptions from the same office?

A Yeah, there was some that were doing that.

Q And would that -- would you consider that to be a pill mill or possibly a pill mill when you saw that sort of activity?

A You know, not necessarily a physician dispensing medication out of his office would be a pill mill. Some -- you know, I can think of one down in a rural area down in Columbia, and they said we did it for the convenience of the patient not having to drive a distance to a pharmacy. Whether I believed all that, I don't know, and I don't recall the profit they would make an dispensing of meds, but that is not a blanket answer for a pill mill.

Q Right. But if you saw that sort of situation maybe where the prescriber would take only cash payments to see the patient, might not do a thorough exam and would just write a prescription for an opioid and then dispense it from his or her office, would that be a sort of definition of a pill mill, in your view?

A Yes. I had a large case involving a diet doctor doing that.

Q Okay. What about -- you said a diet doctor. Was the diet doctor prescribing opioids or diet pills?

11:02:58 **A** He was prescribing amphetamines.

Q Did -- what about the situation where doctors were prescribing opioid pills, was that something you ever came across in your career at the BOP?

A I had doctors prescribing lots of things in my career

11:03:16 at the BOP.

Q Let me --

A Opiates included.

Q All right. Let me turn to something that we talked about a bit before, you touched on a bit before that I now

11:03:33 want to dive into a bit, and that is the jury's heard about and we've now mentioned a former doctor in Ohio named Peter Franklin.

You remember him?

A Very well.

11:03:44 **Q** And we've heard about a pharmacy in Trumbull County called Overholt's Pharmacy. You're familiar with that pharmacy when it existed?

A Very well.

Q Were you, sir, involved in an investigation into the

11:04:00 activities of Dr. Franklin in the 2008 time frame?

A I was.

Q Were you also involved in an investigation in the activities of Overholt's Pharmacy in that same time frame?

A I was. I wrote the primary investigative reports and search warrants.

Q Can you tell us why it was that you were -- you began or undertook an investigation, first, of Dr. Franklin?

A Well, Dr. Franklin -- and I believe his office was up in Geauga County which wasn't one of the counties I was responsible for, it was another agent.

My understanding was numerous pharmacists up there had complained about this doctor and nothing was being apparently done. So I received a call from a specialist in my office, her name was Joanne Perdina (phonetic), who was at it was either Lake -- I think it was at Lake County jail about a patient that's in there and he was getting --

MR. WEINBERGER: Objection to hearsay.

THE COURT: Well, yeah. Sustained as to all this hearsay.

THE WITNESS: Okay. Sorry.

BY MR. SWANSON:

Q No. That's okay. I need to ask better questions to make sure that we're eliciting only responses that you're able to give.

Did you learn anything about Dr. Franklin's

prescribing habits that led you to investigate him?

A I did.

Q What did you learn?

A I learned he was -- my direct information was that he was heavily prescribing controlled substances to a number of patients.

Q And can -- prescribing controlled substance isn't in and of itself unlawful. Was there something about his prescribing that led you to your investigation?

A His prescribing didn't even come close to legitimate medical purpose. He was prescribing exorbitant amounts, numbers I have never seen in my life, to patients controlled substances.

Q Can you give us a sense for what it means to you as an investigator, what constitutes an exorbitant amount of opioids?

A Well, there was one patient, I'll refer to him as Joey, he was getting 900 tablets of Dilaudid, 8-milligram, top strength, a month. That's 30 tablets of Dilaudid, 8-milligram, a month. Not counting oxycodone, methadone, might have been hydrocodone in there and Valium. Enough to kill a herd of elephants, in my opinion, much less a patient. That's one case.

And there was another I could think of, a patient in there, last name started with a V. He was getting 3

strengths of Duragesic patches to apply two patches at a time of each strength, so that's six patches of Duragesic, which is fentanyl, and he was also getting prescribed, I believe, oxycodone or methadone and something else along with it. Enough to kill an elephant also in my opinion.

Q So --

A Those are two examples of Peter Franklin.

Q Okay. And I appreciate that.

What about -- why was it that you were also investigating Overholt's Pharmacy at that same time?

A I wasn't. I -- I was tied up at that time also on the internet case, which took a lot of work. I received a call from another agent -- specialist in my office and said, look at this profile, and it was Joey's. I -- I couldn't believe it. I -- I -- I said, there's something wrong here. And I found out, the profile was from Overholt's Pharmacy, which immediately I shifted into first gear and decided I got to go up there and look at this, which I did.

Q Did the -- did the Board of Pharmacy combine its investigation that you were conducting of Dr. Franklin with its investigation of Overholt's?

A What happened was my field supervisor -- well, my agent supervisor in Columbus, Bob Cole, and then my field supervisor for Northeast Ohio, Jim Rye met me and said you know you're leaving --

MR. WEINBERGER: Objection. Objection, Your Honor.

MR. SWANSON: Let me --

BY MR. SWANSON:

11:09:16 **Q** And again, I apologize, Mr. Pavlich. I need to ask you sort of questions to lead to these answers.

So my first question is just generally, were the investigations of Dr. Franklin and Overholt's Pharmacy, were they ultimately combined?

11:09:31 **A** Yes.

Q Were you -- was that unusual that an investigation of a doctor and a separate pharmacy would be combined into one?

A It was unusual because it was two counties and one of which I was not responsible for.

11:09:51 **Q** Were you the lead investigator into this investigation into Dr. Franklin and Overholt's?

A I was.

Q And what was the connection between Dr. Franklin and Overholt's Pharmacy that led the BOP to combine those two

11:10:05 investigations into a single one?

A I guess my ability to put big cases like that together. I was assigned, and one of the -- the pharmacy was in my county, so the doctor was in another agent's county, but I got the task.

11:10:25 **Q** But was there -- was there some connection between

Dr. Franklin and Overholt's that made it make sense to investigate those two together?

A Yes.

Q What was that?

11:10:39 **A** Dr. Franklin's office in Geauga -- there was numerous pharmacies around his office. I believe there was a Giant Eagle across the street, there was a Rite Aid down the street, there -- there might have been a Walgreens up there and another big pharmacy. The patients were not going to

11:11:04 these pharmacies; they were driving -- I'm guessing if I recall -- 35 minutes south to Trumbull County in Champion, Ohio, and filling their prescriptions at that independent pharmacy. That was the connection.

Q In your investigation, did you learn why it was that

11:11:27 the patients or many of the patients were taking prescriptions from Dr. Franklin to Overholt's?

MR. WEINBERGER: Objection.

THE COURT: Yeah. Sustained.

BY MR. SWANSON:

11:11:40 **Q** Did -- did you, in this investigation, did you -- did you collect evidence?

A A lot of it.

Q Did you collect prescriptions from Dr. Franklin's office?

11:11:55 **A** A lot of them.

Q Did you collect prescriptions from Overholt's Pharmacy?

A I didn't -- backing up. I didn't collect prescriptions from Dr. Franklin's office, patient records. Overholt's Pharmacy, I collected prescriptions.

Q And did you learn anything, as you went through the prescriptions, that connected Overholt's Pharmacy to Dr. Franklin?

A Yes.

Q What did you learn?

A That they were not questioning anything prescribed, they were just dispensing them --

MR. WEINBERGER: Objection -- objection. Hearsay, Your Honor.

THE COURT: Sustained.

BY MR. SWANSON:

Q Well, let me see if I can show you --

THE COURT: Well, let's go on the headphones a minute.

MR. SWANSON: Yeah.

(Proceedings at sidebar.)

THE COURT: All right. Mr. Swanson, I don't know exactly where this is going. If this witness conducted an investigation that led to a prosecution of Overholt's or Franklin or --

MR. SWANSON: Correct.

THE COURT: -- a disciplinary proceeding of Overholt's or Franklin, you can bring that out from him.

MR. SWANSON: Yes.

11:13:17 THE COURT: All right. But -- but -- I'm not going to let him relate what people told him and --

MR. SWANSON: Here's the thing that's important, Your Honor, that I think is admissible. The -- Dr. Franklin, he's testified in his deposition, so I know

11:13:30 this to be true. Dr. Franklin was writing prescriptions and he was writing on the prescriptions, fill only, fill only at Overholt's. That's what he was writing on the prescriptions. That's the testimony that I want to elicit from this witness because I think it's important.

11:13:51 THE COURT: Well, was -- well, was the prosecution of Franklin tied to Overholt's? Were there two separate prosecutions?

MR. SWANSON: Whether the prosecutions were tied, I don't know, but the investigation was tied.

11:14:04 THE COURT: Well, he's already said it was a joint investigation.

MR. SWANSON: Correct, and I'm trying to establish the connection, why it was that he was looking at both Overholt's and at Dr. Franklin.

11:14:14 And separately, I want to say, I have a --

THE COURT: Well, if -- he -- you can ask him -- I mean, do you know why the investigations were consolidated, and if he says yes -- I'm not going to let him relate what people told him, but if he found or was given a whole bunch of prescriptions that Franklin's patients filled at Overholt's, that's the reason why the two were tied together, and he can testify that's what he found.

MR. SWANSON: Right. But, Your Honor, he saw -- here's what I want to ask him. He saw the prescription that said from Dr. Franklin, direction, fill only at Overholt's. I want to elicit that testimony. I think I'm entitled to.

THE COURT: Well, if he -- if he uncovered that in his investigation, then you can bring that out. If that's what he personally uncovered --

MR. SWANSON: So can I ask -- I don't want to run afoul. Can I ask him, did you learn that Dr. Franklin was directing his patients to go to Overholt's?

I have a good faith basis to ask that question because he testified to that in his deposition.

THE COURT: Well, it's leading.

MR. WEINBERGER: It's still hearsay. It doesn't cure it that he --

THE COURT: Well, no, that isn't hearsay. If he found it -- Mr. Weinberger, if he actually uncovered the

prescriptions which said that, he can say I, you know, here are the prescriptions and this is -- I followed this lead. So -- so --

MR. WEINBERGER: Okay.

11:15:39 MR. SWANSON: If I can ask him that question, I can move off --

THE COURT: Why don't you do it this way: Ask him, as part of your investigation, did you -- did you look at prescriptions that were filled at Overholt's, yes or no? 11:15:53 All right? Did you look at which doctors, you know, wrote them? All right? Was one of them Franklin, or something like that? I mean, he can testify to what he personally investigated.

MR. SWANSON: Right. But he's already 11:16:09 testified to that. What I want to elicit is the testimony that they were directed to go to Overholt's.

THE COURT: Well, he doesn't know if they were directed.

MR. SWANSON: Sure he does.

11:16:18 THE COURT: If he's got -- if he saw documents, and the document says fill only at such and such, he can say what the document said.

MR. SWANSON: Your Honor, I have a search warrant that he wrote where he puts that in the search 11:16:29 warrant, so I can just put that in if that's the way to do

it. I'm fine with doing that.

THE COURT: Okay.

MR. WEINBERGER: But it's still hearsay.

MR. SWANSON: No, it's not.

11:16:37 MR. WEINBERGER: Whether it's a --

THE COURT: You can elicit from him that one of the reasons two investigations were put together is that he found in the course of his investigation a significant number of prescriptions at Overholt's -- that were written

11:16:54 from Franklin's office, fill only at Overholt's. You can -- you can bring that out.

MR. SWANSON: I can ask that. Okay.

THE COURT: Yes.

MR. SWANSON: Thank you.

11:17:19 (In open court at 11:16 a.m.)

BY MR. SWANSON:

Q Mr. Pavlich, returning to your testimony, I believe you said that as part of your investigation you pulled prescriptions written by Dr. Franklin that were filled at

11:17:32 Overholt's.

Is that -- is that fair?

A Correct.

Q And it sounds like you reviewed a number of those prescriptions in your investigation?

11:17:44 **A** I did.

Q In looking through those prescriptions, did you see any prescriptions that stated that the prescription should be filled only at Overholt's?

MR. WEINBERGER: Objection, Your Honor.

11:17:56 THE COURT: Overruled.

THE WITNESS: I did.

BY MR. SWANSON:

Q Was that just on one prescription or was that on many prescriptions?

11:18:07 **A** I don't recall how many, but I saw them on numerous prescriptions.

Q And was that suspicious to you in any way?

A Absolutely.

Q The -- as part of your investigation into Dr. Franklin and Overholt's, did you retain or did the Board of Pharmacy retain any medical experts to help you evaluate the legitimacy of the prescriptions you were looking at?

A I did.

Q I've heard mention of a doctor named Dr. Piszel.

11:18:47 Do you know him?

A He was medical expert for me on that case. I believe he was a pain management specialist out of Lake County.

Q But when you say that case, is Dr. Piszel someone that you or the Board of Pharmacy retained to help you

11:19:09 investigate Overholt's and Dr. Franklin?

A I asked him to look at prescriptions and patient profiles for numerous patients of Dr. Franklin dispensed out of Overholt's Pharmacy.

Q And you considered Dr. Piszel to be an expert in pain management and evaluating legitimate prescriptions?

A I did.

Q Did -- well, I want to be careful. Let me look at my notes.

Do you recall having -- in your investigation of Overholt's and Dr. Franklin, do you recall having discussions with pharmacists at the chain pharmacies regarding what they were seeing coming in from Dr. Franklin?

A I did interview chain pharmacists, yes.

Q Do you remember a Walgreens pharmacist by the name of Doug Stossel?

A No. I can't say I do.

Q Let me -- let me see if I can just refresh you. I'm not going to put the document up, but if you look at what's marked behind Tab 4 in your binder.

A Okay.

Q And does this look like the search warrant you wrote up regarding your investigation of Dr. Franklin and Overholt's?

A Yes, sir. This is it.

Q Okay. And it's a long document, but if you turn to

Page 31, at the very bottom and the top of Page 32, can you just go ahead and read that to yourself and see if that refreshes your recollection?

A Wait a minute.

11:21:11 **Q** Yeah, please take your time.

A Wait a minute. I'm trying to find the page numbers here.

Where's the page numbers here?

Q You know, we may have different numbers?

11:21:19 **A** Oh, I see it. I see it. I see it now.

So which numbers?

Q Page 31 and top of 32.

A 31. 32.

Okay.

11:21:38 **Q** And if you just read -- read that your yourself, I just want to ask you if reading that refreshes your recollection of interacting with a pharmacist at Walgreens named Doug Stossel.

(Brief pause in proceedings).

11:22:23 THE WITNESS: I sort of remember this conversation, and I had this with other pharmacists, too.

BY MR. SWANSON:

Q Well, let me ask you --

MR. WEINBERGER: Objection.

11:22:31 MR. SWANSON: I didn't ask with about a

conversation.

BY MR. SWANSON:

Q Just let me take it piece by piece, Mr. Pavlich.

Did you have in -- during your investigation, did you have discussions with pharmacists, including Mr. Stossel at Walgreens?

A Yes.

Q Do you recall that there were questions that were coming to you from pharmacists about what they should do if they were presented with a prescription from -- well -- I'm sorry, let me take a step back.

Did you learn in your investigation that pharmacists, including pharmacists at the chain pharmacies, were questioning prescriptions that they were getting from Mr. Franklin -- Dr. Franklin?

MR. WEINBERGER: Objection.

THE COURT: Overruled.

THE WITNESS: Yes, they were questioning them.

BY MR. SWANSON:

Q And were they asking you what -- what, as a Board of Pharmacy agent, what they should do with the prescriptions that they were getting from Dr. Franklin?

A Yes.

Q Did you -- and was Doug Stossel one of those pharmacists?

A I documented it, yes.

Q And did you tell pharmacists at the chain pharmacies who had this question that they could continue to fill prescriptions --

11:23:56 THE COURT: Let's see if we can do this in a non-leading way. First establish if he gave him the advice.

MR. SWANSON: Thank you, Your Honor, and I'll do that.

BY MR. SWANSON:

11:24:05 **Q** When they asked you this question, what did you tell them they should do?

A I told them dispense prescriptions from any prescribers if you have legitimate medical purpose. But if you have concerns, don't dispense. You have a corresponding

11:24:23 responsibility. My set answer to numerous questions about things like that.

Q Okay. And what -- do you recall what Doug Stossel concluded?

MR. WEINBERGER: Objection.

11:24:34 THE COURT: Sustained.

BY MR. SWANSON:

Q The -- let me ask you a different question.

When you told -- when you told pharmacists that they could continue to fill prescriptions if they thought they

11:24:54 had a legitimate medical purpose, did that include

prescriptions that came from Dr. Franklin?

A Yes. There were some.

Q So even though you had concluded -- or were investigating what you considered to be potentially criminal prescribing from Dr. Franklin, was it your view that he was also writing some prescriptions for patients that had a legitimate medical need?

A Yes.

Q Was Dr. Franklin, was he eventually indicted, do you recall?

A What I recall was I was preparing the Indictment with the Geauga County prosecutor in conjunction to my investigation, and Dr. Franklin was stabbed to death by his office manager wife.

Q And --

A And that concluded that.

Q So he was -- I interrupted you at the part that was important. So it sounds like he was murdered by his office manager, ex-wife?

A His office manager and actual wife. Not ex.

Q Not ex. Okay. And that was before he could be indicted?

A Yes.

Q What about -- what happened to Overholt's Pharmacy?

A Well, at that point in time, I always go after the

prescriber first and then pharmacists after or stores after, so I was putting the case together as one. I went after the pharmacy and the pharmacist and brought it to the attention of Dennis Watkins, Trumbull County prosecutor.

11:26:45 **Q** Do you know what ultimately became of Overholt's Pharmacy?

A They lost their license and all three pharmacists lost their personal practicing license and they were all convicted of felonies.

11:26:58 **Q** As an agent for the Board of Pharmacy, do you have a view of whether Dr. Franklin's activities contributed to the opioid problem in Northeast Ohio?

MR. WEINBERGER: Objection.

THE COURT: Overruled.

11:27:19 THE WITNESS: I do believe they contributed greatly to the activity in that county and counties.

BY MR. SWANSON:

Q And as a member of the Ohio State Board of Pharmacy, do you have a view of whether the conduct of Overholt's Pharmacy contributed to the opioid problem in Northeast Ohio?

MR. WEINBERGER: Objection.

THE COURT: Overruled.

THE WITNESS: I do agree.

11:27:40 MR. SWANSON: Mr. Pavlich, thank you very much

for answering my questions. I'm going to pass you off now to the plaintiffs' lawyer.

THE COURT: Okay. I just want to make sure there weren't any other questions from any of the other defendants.

MS. FUMERTON: No, Your Honor.

MR. DELINSKY: No, Your Honor.

THE COURT: Okay. All right.

Mr. Weinberger.

CROSS-EXAMINATION OF GEORGE P. PAVLICH

BY MR. WEINBERGER:

Q Mr. Pavlich, good morning. Can you see me?

A I can.

Q Okay. My name is Peter Weinberger. We had a chance to meet on Zoom when a number of the defense counsel and I took your deposition some time ago.

Do you remember that?

A I do.

Q So, first of all, you have not been employed by the Ohio Board of Pharmacy since 2012; right?

A March 1st, correct.

Q Right. Now, you had a long and storied career there for 25 years, and we all certainly appreciate the service that you rendered on behalf of the Ohio Board of Pharmacy.

I want to go directly to your testimony about

Dr. Franklin.

Now, you testified that you pulled the prescriptions from his office and from the Overholt's Pharmacy as part of your investigation; correct?

11:29:49 **A** No. I corrected that. I said I obtained patient records from his office and pulled prescriptions from Overholt's Pharmacy.

Q Right. And I'm assuming that as a good and competent investigator investigating now 90 doctors or so over your

11:30:09 career, you would have also wanted to know whether or not -- or what the prescriptions that were filled at other pharmacies from Dr. Franklin would have looked like; right?

A Yes.

Q And so I'm assuming that you pulled the prescriptions

11:30:26 that Dr. Franklin wrote from the Walgreens stores in Trumbull County; right?

A I don't recall if I pulled them. I surveyed the files at all the pharmacies up in Geauga County and did not find anything that would result in me, I believe, pulling

11:30:48 prescriptions.

Q Well, I'm not talking about Geauga County where Dr. Franklin was, because you told us that your concern was, or the thing that flagged or raised concerns initially was here it was Dr. Franklin, who was in Geauga County, his

11:31:07 patients were going elsewhere outside of Geauga County,

including to Trumbull County; right?

A Yes.

Q So that's my question. Did you go to the Trumbull County pharmacies of these defendants, CVS, Walgreens, and Walmart, and ask for their -- the prescriptions that they filled on behalf of Dr. Franklin's patients?

A I surveyed numerous pharmacies in Trumbull County, yes.

Q Okay. Well, surveying is different than pulling the prescriptions, sir. I mean, I understand -- wait. Let me finish.

I understand that, for example, when you did inspections, you did this -- you surveyed their files, and we'll get to that later. My question is, as part of your investigation that led ultimately to the downfall of Dr. Franklin, did you actually ask the Walgreens pharmacy, for example, in Trumbull County, for copies of their scripts that they filled on behalf of Dr. Franklin's patients?

A I don't recall pulling -- original prescriptions out of any other pharmacies related to Dr. Franklin. I looked at other pharmacies, but only pulled them from Overholt's Pharmacy because that's where they all were.

Q Well, that's not true, is it, sir? There were a lot of -- there were a lot of prescriptions filled by Trumbull County Walgreens stores written by Dr. Franklin.

Isn't that true?

MR. SWANSON: Objection, Your Honor.

THE COURT: Overruled.

MR. SWANSON: Foundation.

11:32:58 THE COURT: Overruled.

THE WITNESS: Not to the extent of what I saw at Overholt's Pharmacy or the manner of issuance versus quantity and specific patients.

BY MR. WEINBERGER:

11:33:11 **Q** Well, sir, did your investigation reveal that between 2006 and 2009 that Walgreens filled 1,250 Franklin prescriptions totaling over a hundred thousand pills?

MR. SWANSON: Objection, Your Honor.

THE COURT: Overruled.

11:33:37 THE WITNESS: A hundred thousand pills are not that much if you think about it. If a patient's getting six tablets a day --

THE COURT: Well, first of all --

THE WITNESS: -- 4 hours for pain.

11:33:48 THE COURT: Hold it. Hold it. Hold it, sir.

Can you answer the question?

THE WITNESS: Yeah. I -- I don't know what he's talking about. I would have pulled the prescriptions if I found a legitimate -- illegitimate medical purpose.

11:34:02 BY MR. WEINBERGER:

Q Well, you just told me that you surveyed the prescriptions, the Dr. Franklin prescriptions, but you didn't pull any; right, from Trumbull County, from the Walgreens store in Trumbull County?

11:34:15 **A** Yes.

Q Right? That was your testimony; right?

A Yes.

Q Okay. So are you aware of the fact that in this case the defendants were required to turn over their dispensing

11:34:28 records and their data for their stores in Trumbull County? Are you aware of that?

A Turn them over to who?

Q To us. To the plaintiffs' lawyers in this case on behalf of these two counties, Lake and Trumbull County.

11:34:44 You understand that's who we're representing sir?

A Yes, I understand who you're representing.

Q All right.

A And I understand you have records. Okay.

Q Okay. All right. So let me show you --

11:34:59 If we can get the Wolfe Vision up and operating.

(Brief pause in proceedings).

MR. WEINBERGER: Mr. Joyce, we're having some technical difficulties -- I mean, Mr. Pavlich, we're having some technical difficulties.

11:36:25 THE COURT: We're trying to show you a

document, sir.

MR. WEINBERGER: I'm sorry?

THE COURT: I'm just telling the witness we're trying to show him a document.

11:36:36 MR. WEINBERGER: There we go.

BY MR. WEINBERGER:

Q So this is demo 071, sir. And what I'd like you to look at is this -- this is information that we got from the dispensing records of these three defendants.

11:36:58 MR. SWANSON: Objection, Your Honor.

Can we be heard on this?

MR. STOFFELMAYR: Take it down, please.

MS. FUMERTON: Would you take it down?

(Proceedings at sidebar.)

11:37:31 MR. SWANSON: Your Honor, I showed the witness an official task force report that Mr. Weinberger objected to. He said he's never seen it. So I asked the witness if he had seen it and he said no and I took it down.

They're now trying to show him documents that were

11:37:47 created for litigation by an expert that he -- I can promise you has never seen before.

THE COURT: Well, I -- look, you -- Mr. Weinberger, you asked him do you know -- did you -- first of all, he said he didn't pull any of those records. All right? He said he didn't -- he didn't pull them. All

11:38:03

right? You asked him about, you know -- do you know that these other pharmacies filled prescriptions -- 1,250 prescriptions, that's just Walgreens --

MR. WEINBERGER: Yes, Your Honor.

11:38:22 THE COURT: -- filled 1,250 prescriptions, over a hundred thousand pills. He said a hundred thousand pills aren't that much. Basically he said he doesn't know that.

So I don't think you can show this document. You've 11:38:32 established that he didn't -- he didn't care enough to even pull them, so, that's it.

MR. SWANSON: And, Your Honor, can I add that I think it's improper to suggest in a question that evidence doesn't exist for which the witness has no foundation. It's 11:38:44 not a proper question to say, did you know there were 1,250 prescriptions filled if there's no foundation for it. You can say, do you know how many prescription were filled, and when he says no, you can't then suggest the answer because there's no foundation. I think that's improper.

11:38:58 MR. WEINBERGER: Your Honor, this is --

THE COURT: Mr. Weinberger has his foundation. He knows it for a fact that they were filled, so he can ask the -- I mean --

MR. SWANSON: But the witness needs the 11:39:07 foundation, not Mr. Weinberger.

THE COURT: Well, the witness would have had a foundation if he pulled it, so -- and maybe he looked, I don't know, so I think -- I think you pretty much exhausted this subject with this witness, Mr. Weinberger.

11:39:17 MR. SWANSON: Thank you, Your Honor.

(In open court at 11:39 a.m.)

BY MR. WEINBERGER:

Q Mr. Pavlich, do you know where Walgreens Store 11730 is?

11:39:42 **A** No.

Q Do you know that it's in Trumbull County -- well, let me ask you this. Assume it's in Trumbull County, okay? Assume that for the moment.

A Okay.

11:39:54 **Q** Now, you testified earlier that you knew Mr. Brian Joyce; right?

A Correct.

Q And you testified about you thought he was a good pharmacist and the work that he did and your relationship

11:40:05 with him; correct?

A Correct.

Q I want you to assume that he was the pharmacy supervisor for this particular store in Trumbull County in 2006 to 2009.

11:40:22 Fair enough? Will you assume that for me?

A Okay.

Q So at any point in time did you have any -- while you were doing the investigation of Dr. Franklin, did you ask Brian Joyce, as the pharmacy supervisor for Walgreens, whether he or any of the pharmacists in his store had any experience filling Dr. Franklin's prescriptions?

A I don't recall a conversation.

Q Well, are you familiar with a Dr. Feres [sic], F-e-r-e-s?

A It doesn't strike a bell with me.

Q We heard testimony from Mr. Joyce that Dr. Feres, for 25 years, was a high-volume prescriber of opioids in Trumbull County.

Did Dr. Joyce -- did Mr. Joyce ever tell you that -- Dr. Veres is the doctor's name we're talking about.

THE COURT: Veres?

MR. WEINBERGER: V-e-r-e-s.

THE COURT: V-e-r-e-s, sir.

THE WITNESS: I recall a Dr. Veres, yes.

BY MR. WEINBERGER:

Q Well, did you ever investigate Dr. Veres?

A I believe myself and another specialist went to his office a number of times, yes.

Q And did you learn that he was a high-volume prescriber of opioids?

A I don't remember what I learned at that point.

Q Did you ask Mr. Joyce to pull the prescriptions from Walgreens that were filled from Dr. Veres' prescriptions?

A I may have. I don't recall.

11:42:18 **Q** So you don't recall anything more about this investigation of Dr. Veres, other than the fact you visited his office on a couple of occasions?

A Yeah. I -- I know I didn't pursue a criminal case, so --

11:42:34 **Q** Did you become -- did you become aware of the fact that CVS and Walmart at some point in time refused to fill prescriptions written by Dr. Veres?

A No, I don't recall.

Q Did -- do you recall learning from Mr. Joyce that

11:42:55 despite the fact that CVS and Walmart were not going to fill any more prescriptions of Dr. Veres, that Walgreens, nonetheless, continued to fill those prescriptions?

A I don't recall.

Q So, I understand from your testimony, sir, you were --

11:43:25 you were a very busy field agent for the Ohio Board of Pharmacy during your tenure there; right?

A I was.

Q Received lots of calls pharmacists; right?

A Right.

11:43:41 **Q** Investigated 80 or 90 doctors; right?

A Prescribers, yes.

Q Right. Well, doctors, prescribers, right. And did -- was this all encompassed within your territory; sir?

A No.

11:44:00 **Q** So you investigated doctors outside of your territory?

A Yes.

Q How far out -- let's, first of all, talk about your territory.

What was your territory during your tenure as a field

11:44:12 agent?

A During my entire tenure or just the last few years?

Q Well, let's talk about the last 10 years.

A Trumbull, Mahoning, Columbiana, and Jefferson County.

Q How many pharmacies -- how many individual pharmacy

11:44:35 stores are there in that four-county area?

A I have no idea. I'd be guessing.

Q Well, you did -- you told us that you did 50 inspections a year, or you were supposed to, right?

A I was supposed to.

11:44:50 **Q** Well, was there some years that you weren't able to do the full 50?

A Yes.

Q Because you were busy with other things and other investigations. True?

11:44:58 **A** True.

Q Well, are there more than 50 -- were there more than 50 pharmacy stores or pharmacy locations within your four-county area?

A Yes.

11:45:12 **Q** So would it be fair to say that you -- even in the years where you were able to do 50 inspections, you did not inspect, on an annual basis, every store within your territory; correct?

A Absolutely correct.

11:45:31 **Q** Um-hmm. There were some stores where it would be maybe 18 months or two years before you would inspect them; right?

A Could be.

Q And when you first started out at the Ohio Board of

11:45:44 Pharmacy, there were only eight field agents; right?

A That's probably accurate, yes.

Q So you were spread even thinner back at that time; right?

A Yes.

11:45:58 **Q** And then as years went by, there were additional field agents that were hired, and I think you said at the point of your retirement there were about 15 field agents; right?

A Yeah, I'm approximating about that much.

Q Um-hmm. And when you left in 2012, in March of 2012,

11:46:21 isn't it true that you and the other field agents felt you

were -- that they were overworked, that you and they were overworked?

A I don't know -- I don't have an answer for that.

Q Well, do you remember about a month before you left the Ohio Board of Pharmacy there was a survey sent out by the Ohio board surveying the field agents?

A No, I don't recall that.

Q Um-hmm. So didn't you feel, from your perspective, that the Ohio Board of Pharmacy should hire more field agents so that you could concentrate more within your counties that you were assigned to and do the job that you were tasked to do?

A I would say that would be correct.

Q Um-hmm. Now, you told us that your inspections -- the full inspections, the 50 or fewer that you would perform every year, would take about 2 and a half to 3 hours; correct?

A Normally. Not all the time.

Q And so sometimes it would be more, but sometimes it would be less; right?

A Right.

Q And would it be fair to characterize these inspections as a 2 and a half to 3-hour snapshot of the conditions at that pharmacy?

A Yes.

Q A 2 and a half hour -- 2 and a half hour to 3-hour snapshot once, perhaps for that particular store, every year, 18 months, two years; right?

A Yes.

11:48:24 **Q** So you're not suggesting, are you, sir, that that 2 and a half to 3-hour inspection provides us with a complete and accurate picture of how the pharmacy operates on the other 364 days or more; right?

A I'm not suggesting anything.

11:48:50 **Q** Okay. Now, you told us that your inspection includes inspecting whether or not there was appropriate security; right?

A Correct.

Q Whether or not there were barricades; right?

11:49:06 **A** Correct.

Q And you told us -- and I wrote this down -- that you also looked at the controlled substance prescription files; right?

A Yes.

11:49:25 **Q** And there were separate files for the C-IIs and then separate files for the C-IIIs, IV, and Vs; right?

A Correct.

Q And you told that us during this 2 and a half hour to 3-hour inspection, you would look at the separate files for

11:49:45 the C-II controlled substances and you would spend about a

half hour looking at those files; right?

MR. SWANSON: Objection. Mischaracterizes.

MR. WEINBERGER: I thought. Maybe I wrote it down wrong. I thought you looked at each of the C-II files --

11:49:58

THE COURT: Well, overruled. You can ask him if that's what he said. If it's different, it's different.

MR. WEINBERGER: I'll withdraw the question. Let me ask it.

BY MR. WEINBERGER:

11:50:05

Q With respect to the Class II scripts, which are the OxyContins, the oxycodones and the like, you would take about a half hour to look at these files; right?

A I'm approximating it on a normal basis.

Q Right, and this is a half hour out of the 2 and a half hour to 3-hour inspection; right?

11:50:25

A Yes.

Q And you told us that you had 3 years of scripts to look at?

A I told you that the pharmacy was required to maintain records for a minimum of three years.

11:50:48

Q Well, when you would do this review, how big were these -- these record files that you were looking at?

A It all depends how many prescriptions they dispensed on a daily basis in that pharmacy.

11:51:11

Q Well, were you looking at a day's worth of prescriptions of controlled substance prescriptions or more than a day?

A I would go back as far as I felt necessary to get a good picture of what they were dispensing.

Q Well, so would you go back a week? 2 weeks? A month? A year? How long? How far back?

A All of the above probably.

Q Well, you know, if -- if the store -- you said sometimes fill 500 controlled substance prescriptions a day; right?

A Right.

Q So when you would go to your -- to do your 2 and a half hour inspection, I'm assuming you would have to go to file cabinets worth of scripts in those stores to really look at them carefully; right?

A That's right.

Q So that's what you would do, you would look through file cabinets of stores -- of scripts?

A Right.

Q And tell me your process for doing that.

Did you -- did you just kind of leaf through and pull out one or two scripts and look at them?

A I would take packets of prescriptions from that day and then leaf through them for different periods of time,

maybe the next day, maybe the next week, maybe the next month, maybe 6 months. It varied.

Q Okay.

A But I would get a snapshot of what was going on.

11:52:58 **Q** So did you keep any records, Mr. Pavlich, of your doing -- of specifically what you did that we could look at and see the documentation for the inspection, other than these inspection reports?

Did you actually compile information or statistics or 11:53:19 data as to what you were looking at?

A Yes. When I conducted a criminal investigation, the prescriptions were listed in the criminal investigation.

Q Okay. Well, we're not talking about a criminal investigation, we're talking about your 2 and a half hour 11:53:38 inspection that you would do every year or two years for let's just say the Walgreens store in Trumbull County.

Did you keep any records, sir, of how many scripts you actually looked at when you were looking through these files?

11:53:52 **A** No.

Q Well, you told us that some of these pharmacies dispensed 500 or more controlled substance prescriptions a day; right?

A That was just a number I threw out there.

11:54:12 **Q** Well, was it a right -- correct number or was it not

correct?

A Well, there was some pharmacies that probably dispensed more than that, and there was a lot of pharmacies that dispensed less than that, and the half an hour time that I talked about looking at C-IIs depended on the volume of prescriptions, which I believe I testified to.

Q So did you ever look or obtain any information as to the actual volume of opioid pills dispensed at a particular store on, say, a monthly or yearly basis?

A If I was doing an audit I would.

Q Well, how -- what's an audit?

A A total accountability for all the prescription medication that I specifically look at during a set period of time, usually a controlled substance.

Q How many audits would you perform a year?

A 10.

MR. SWANSON: Your Honor, I'm sorry to interrupt. We've lost our realtime. I think everybody has.

THE COURT: All right. Robert, can you see if you can fix this?

(Court reporter clarification.)

MR. WEINBERGER: May I proceed?

THE COURT: Yes.

BY MR. WEINBERGER:

Q So 10 audits per year for your territory or beyond

your territory?

A That's a number I'm giving. It -- I would assist in other agent's audits, not mine specific. I mean, it could be 5 a year, it could be 10. It varied. Depends what kind of investigation I'm conducting. I didn't do it just to do it.

Q Well, in order for you to determine the validity of your inspection of these hard copies of the scripts at a particular store, wouldn't you want to know some idea -- have some idea of the volume of controlled substances prescriptions for that store?

A Sure. I could easily see that.

Q Well, would you -- would you know what the volume of any of the Walgreens stores in Trumbull County were on an annual basis?

A An annual basis?

Q Sure.

A I would have to do some extensive review to get that.

Q Which you never did, did you?

A I conducted audits in Walgreens for drugs.

Q My question is --

A I don't recall. I don't recall.

Q Okay. So let's talk about -- let's talk about -- you've talked a little bit about your 2 and a half or 3-hour inspections. Let's talk about what it might not have

included. Okay.

Did your investigation or your inspections include a review of the pharmacy's written dispensing policies for controlled substances?

11:58:03 **A** I don't recall seeing written dispensing policies.

Q So the answer would be no, you didn't -- you didn't look at Walgreens or CVS's or Walmart's --

A I don't know.

MR. SWANSON: Objection, Your Honor.

11:58:15 THE WITNESS: I don't recall. That's --

THE COURT: Overruled.

BY MR. WEINBERGER:

Q Did you --

A I don't recall.

11:58:20 **Q** Did your inspection include a review of any of the training programs that Walgreens or CVS or Walmart had for their pharmacists?

A No.

Q Did you ever ask Walgreens or CVS or Walmart to

11:58:44 provide you with dispensing data records regarding the volumes of opioids filled in their stores?

A I asked for records a lot. I don't recall anything specific, though.

Q So you would not have had any accurate picture, during

11:59:15 your inspections, of what the trends were in terms of the

volume of opioid pills dispensed out of any one particular store of these three defendants; right?

A Wrong.

Q So you would have some idea, in your mind, but you hadn't -- you didn't have actual statistical evidence to reach any conclusions about volume -- volumes of pills dispensed trending -- trends; correct?

A No.

Q Okay. Now -- correct? So you agree with that statement?

A No. I don't agree. I don't agree. If I would have saw volumes of pills at a certain location, whether it was a chain or an independent, I would have done something.

Q All right. Well, do you have any records that you can share with us today that reflects your study of data of trends of volumes of pills in any of the stores in Trumbull County that you were in charge of inspecting?

A I'm lucky to have my memory from 10 years ago. I don't have any records.

Q Fair enough, sir.

Do you have any records -- or let me ask you this: Are you familiar with the concept of opioids prescribed in combination with benzodiazapines or a muscle relaxant?

A Yes. It enhances the effect, from my knowledge.

Q Not only does it enhance the effect, it's very

dangerous to the patient; right?

A I -- I agree.

Q Okay. Now, in the course of your doing these spot inspections, looking through these controlled substances files, did you look for prescriptions to the same patient involving all three of those classes of drugs?

A I'm sure I looked for it. I don't recall any specific patient, though.

Q Okay.

MR. WEINBERGER: Your Honor, maybe this is a good time for us to break.

THE COURT: Okay. I was going to suggest it. Okay. Ladies and gentlemen, we'll take our noon hour lunch break. One hour. All the standard admonitions apply. Have a good lunch and then we'll pick up with the balance of Mr. Pavlich.

So, Mr. Pavlich, you can take a lunch break. Please come back at 1 o'clock. Okay?

THE WITNESS: Thank you.

THE COURT: Thank you.

THE WITNESS: Yes, sir.

(Jury excused from courtroom.)

(Recess was taken from 12:02 p.m. till 1:00 p.m.)

AFTERNOON SESSION

(In open court at 1:00 p.m.)

MR. LANIER: Your Honor, when it's appropriate, there's a concern I've got I'd like to put on the record.

13:00:17

THE COURT: All right.

MR. LANIER: It will take 1 minute.

I'm trying to understand the boundaries, recognizing I've got a cross coming up. The witness that's on the stand right now is a fact witness. He's an investigator. Much like Tony Villaneuva was a fact witness and an investigator, but we weren't allowed to get into Mr. Villanueva's investigations that involved the parties in this case, whereas he's allowed to get into investigations that involve parties that aren't in this case.

13:00:29

13:00:50

THE COURT: I'm confused. I've allowed both -- know, we're on cross-examination. I've allowed Mr. Weinberger to ask, you know --

MR. LANIER: Okay.

THE COURT: -- his questions.

13:01:03

MR. LANIER: Okay. I'm trying to -- I don't where to object and where not to object because they're doing the things with their witnesses that I wasn't allowed do with mine. And that's my concern is they've got a guy who's saying I went and investigated all the these

13:01:17

pharmacies and everything was great, and here's the horrible thing that happened and the guy got killed by his wife, and yet I can't put on an investigation file of my fellow and what he did who's hands on in the county as an investigator.

13:01:31 And so I'm just trying to figure it out, but I'll keep working on it.

MR. SWANSON: Your Honor, I asked about -- I didn't put a file in.

(Court reporter clarification.)

13:01:42 MR. SWANSON: I'm sorry. Brian Swanson for Walgreens.

I didn't put an investigation file in. Just like he did with Villanueva, I asked about an investigation that he had direct knowledge of. It's the same thing.

13:01:49 MR. LANIER: I wasn't allowed to ask about the investigation.

MR. SWANSON: Sure you were, and you did.

MR. LANIER: All right. Then maybe I was just brain dead.

13:01:58 All right. Thank you, Judge.

(Brief pause in proceedings).

(Jury returned to courtroom at 1:03 p.m.)

THE COURT: Please be seated, Mr. Pavlich. I want to remind you you're still under oath.

13:04:00 And, Mr. Weinberger, you may continue.

BY MR. WEINBERGER:

Q Mr. Pavlich, can you see me and hear me?

A I can.

Q Okay. In your direct testimony you talked about an extensive lengthy investigation of an internet pharmacy.

Do you recall that?

A Yes.

Q And how much time it took up of your time as a field agent investigator; right?

A Yes.

Q And you talked about how it involved one and a half -- I think one and a half million scripts or pills that were not for legitimate medical purpose?

A One and a quarter doses.

Q Okay. So -- one and a quarter doses, a lot more pills?

A Well, doses are pills, yes.

Q Okay. Sorry.

So you weren't meaning to imply, were you, that this internet pharmacy investigation that -- and the pharmacy that you shut down involved opioids, were you?

A No. I was just talking about -- I was asked about an internet case.

Q Right. So Mr. Swanson asked you about an internet case involving one and quarter dosages or pills, and that

has nothing to do with the opioid crisis, or had nothing to do with the opioid crisis in Northeastern Ohio; right?

A They weren't opioids.

Q So you agree with what I just said; right? It had nothing to do with the opioid crisis?

13:05:47

A Yeah. Yeah, I agree. I agree that it had nothing to do with opiate cases.

Q Okay. Well, I just didn't want the jury to get the wrong impression of that particular investigation.

13:05:59

So as I understand what got you into investigating Dr. Franklin and Overholt's was you got a tip; right?

A I got assigned.

Q You got assigned as a result of a tip that came in; right?

13:06:24

A I didn't get the direct at this point. I got assigned by my supervisors to meet the pharmacist. That's how it happened.

Q Well, Overholt's was in your district; right?

A Yes, it was.

13:06:38

Q And I'm assuming that before this assignment came into you that you had visited the Overholt's Pharmacy for inspections; right?

A I don't recall prior to when I went there on this investigation when I had been there prior to that.

13:07:01

Q But you had been there?

A Oh, I -- yes, I had been there.

Q Multiple times; right?

A Probably.

Q Doing your usual 2 and a half to 3-hour investigation; right -- or inspection, right?

A Not all the time. I might have been there for some other reason, I don't know. I don't recall the last time I was there other than when I went for this investigation.

Q Well, when you would have done your inspection, you would have done your usual thorough job of looking at the script files for the controlled substances; right?

A If I was doing a full inspection, yes.

Q And you would have been looking at the actually physical scripts; right?

A If I was doing a full inspection, yes.

Q And so if you had -- if you had been to Overholt's and had done your usual investigation, I guess you would have seen that the Dr. Franklin scripts had notated on them, only fill at Overholt's; right?

MR. SWANSON: Objection.

THE COURT: Overruled.

THE WITNESS: If I would have saw them, I would have taken action.

BY MR. WEINBERGER:

Q So maybe you were there and you were going through

this file of scripts and you just didn't see a Franklin prescription that said fill only at Overholt's. Maybe you just didn't see it; right?

A No. I don't agree with that comment.

13:08:40 **Q** All right. So when you do do these inspections that includes the review of these hard copy scripts in this file, tell me what you're looking at. Is it one document per script? What do you look at?

A Well, one prescription equals one medication specific

13:09:09 doses and specific directions for a specific patient on a specific date.

Q Okay. So you're -- are you looking at the actual prescription itself that got filled?

A If I'm looking at the prescription files, yes.

13:09:27 **Q** All right. And is there anything -- any other documentation attached to that written prescription that you're looking at in the C-II files?

A There would have been a dispensing computer-generated label affixed to it.

13:09:45 **Q** Anything else?

A Manual initials of the dispensing pharmacist.

Q Anything else?

A Not off the top of my head, no.

Q So you're familiar with the red flag or concern known

13:10:05 as doctor shopping?

A I'm familiar with doctor shopping.

Q Okay. There's no way to determine whether or not the patient whose script was filled that is contained in that file, whether there was a concern about doctor shopping; right? No way to tell from looking at that file; right?

A From looking at the original prescription file you're saying?

Q Yep.

A No. I wouldn't be able to determine that.

Q Okay.

A Unless -- unless the pharmacist made a note of some sort about the patient being at another pharmacy or other doctors, I've seen that.

Q Right. But if such a note was made, you would expect to be some -- be some -- some documentation of the resolution of that concern on the script; right?

A The pharmacist would probably make a notation as to their finding.

Q Um-hmm. And if you looked at just an individual script, as you've described it, in the file, you wouldn't be able to tell whether or not the patient was involved with pharmacy shopping; right?

A No, I would not, unless there was a note.

Q And if you just looked at this particular script, you wouldn't be able to tell whether or not the patient paid

cash for it; right?

A Well. . . let me think about that.

I believe in some dispensing systems the label that was generated by the computer and affixed to the prescription would sometimes indicate an insurance pay or a cash pay.

Q Well, you're just --

A Not in all cases but I recall -- I recall something like that.

Q Seldom happened; right? Seldom noted on the script that you were looking at; right?

A I wouldn't use the word "seldom."

Q All right. Well, you wouldn't be able to tell from the physical script whether or not it was an early refill, right, of a prior script?

A Just by looking at the original --

Q We're talking about the files that you reviewed during your 2 and a half hour inspection. You know, you said you had access back three years, potentially.

Could you -- could you tell whether or not there was an early refill?

A I can tell if you looked back to the prescription prior to that, yes.

Q Well, that would require you to find the prescription for that patient in this file cabinet of physical scripts;

right?

A No, that's not how I would do it.

Q Well, how would you do it, sir?

A Well, I would go in the computer and run that patient's name and see when was the last prescription that they got prior to that one and then I would know the number and I could find the original prescription. That's how.

Q So -- but there would be nothing in this physical file of scripts to alert you that, hey, this is a patient who I got to go to the computer -- and by the way, you said -- you told us you're not particularly computer savvy, but let's assume you could use the computer, what would trigger you, looking at a physical script, to say, hum, maybe this is somebody I should look up for a potential early refill red flag?

A Well, there would be a couple of things: Number one, like I told you, I had lots of phone calls on lots of things. And if I recall the name, that would be a reason that would pique my interest. If I would see a prescription for 900 Dilaudid in a month, that would pique my interest. Various things would pique my interest.

If I saw an alteration on the prescription, that would pique my interest. If I saw a doctor that I might have some information on that I was concerned about, that would pique my interest. Numerous things.

Q And when you would do this, would you document anywhere on your inspection report or in your own documentation that, you know, I looked -- I looked through these big file of scripts, and hey, there was a patient there that I recall from somewhere, so I'm going to go to the computer, I'm going to run that patient's name, and I'm going to look for prior scripts?

Any documentation of that during your inspections?

A Oh, yeah. There was documentation of that during my inspections.

Q And where would we find that documentation, sir?

A Well, sometimes I made manual notes on a notepad. Sometimes I made notes on inspection reports. If you look at the Overholt's inspections, there's lots of notes like that.

Q Sir, the trilogy cocktail, let's talk about that.

So first of all, would benzodiazapines and muscle relaxants, scripts for them, would they be the C-II file?

A They're not C-IIs, I don't believe, so they would not be in the C-II file.

Q Do you know, are they C-IIs or not?

A I don't believe they are, but again, I'm 10 years out.

Q Yeah, so -- so everything that you've testified about that you've -- that you did as a field investigator does not apply to this case from 2012 to now, right, because you were

no longer at the Ohio Board of Pharmacy; correct?

A That is correct.

Q Okay. So you locate an OxyContin script in the C-II file for patient Joe Jones. The benzodiazapines would not be in that file; right?

13:17:16

A No, it would not.

Q The carisoprodol, the muscle relaxant, would not be in that file; right?

A No, it would not.

Q Now, are you familiar with the concept of refusal to fill?

13:17:36

A Yeah. I'm familiar.

Q And are you aware of the fact that there were times when a pharmacy would refuse to fill a prescription of an opioid?

13:17:59

A Absolutely.

Q And did the pharmacies that you inspected keep separate file folders for refusals to fill?

A No. If they had a patient walk in with a prescription and they refused to fill it, they would not keep the prescription, they would hand it back to the patient. It's not their property.

13:18:17

Q So when you would look through and do your inspection, and you would be looking through the C-II files and the C-III to C-V files, you wouldn't see any scripts where the

13:18:39

pharmacy or the pharmacist refused to fill; right?

A No. They would have no reason to be in there.

Q So when a patient goes to a pharmacy and there's something about that script that raises concerns that cannot be resolved and the pharmacist makes a decision not to fill, would that be important information, indeed, would it be a red flag when that same patient arrives at that same pharmacy trying to fill a similar prescription?

A Yeah. If they refused it once, they should refuse it constantly.

Q But when you did your inspections, Mr. Pavlich, you never looked at that issue; right?

A Well, if I didn't see a prescription, how would I look at it?

Q So the answer is, right, you never -- right, Mr. Weinberger, you never looked at that issue during your inspections; right?

A Right, Mr. Weinberger. That's impossible to see.

Q Very good. Thank you, Mr. Pavlich.

When you were looking at the physical script file that was kept at that pharmacy, that would be information -- the filling of those scripts would be information that only that pharmacy would have; right?

A The original prescription would remain in that pharmacy, yes.

Q All right.

A But the information in the chain must be also at their HQ, if that's what you're asking.

Q Yeah. You mean at their headquarters; right?

13:20:51 **A** Yes.

Q When you say "HQ"?

A Yes. Yes.

Q Okay. Now, you told us -- you told us in answer to question on direct examination that, you know, for example, 13:21:07 with respect to Walgreens, you made a notation that they use IntercomPlus for their -- as their system for filling scripts.

Do you recall that?

A Yeah, I believe that was written on there. I don't 13:21:29 recall what I --

Q Okay.

A It was on the -- it was on the inspection sheet, their computer software at that time, yes.

Q Right. But as far as you were concerned, since you're 13:21:40 not particularly computer savvy, you have no idea how that system works; right?

A None. Absolutely none.

Q All right. So let's move to the next subject, Mr. Pavlich, which is OARRS.

13:22:00 You're familiar with the fact that OARRS is the Ohio

Prescription Drug Monitoring Program; right?

A Yes. It came into existence when I was there.

Q Right. Actually, it began in about 2006.

Does that jog your memory, sir?

13:22:18 **A** I don't remember the date, but it came into existence while I was still there, yes.

Q You understand that the laws of the State of Ohio required pharmacies to send their dispensing data for opioids dispensed at the pharmacy to the State of Ohio so

13:22:36 that it could be inputted into OARRS?

A I know that it was downloaded to the Board of Pharmacy, but I had nothing to do with that.

Q And you began using OARRS in your investigation of doctors, patients, and pharmacies; right?

13:22:55 **A** Probably a year after it was first started I began to use it because it was a quick and easy method to look for doctor shoppers for an example.

Q Right. In fact, you found it, I think you told us in deposition, using your words, that it was an enlightening

13:23:20 experience --

MR. SWANSON: Objection, Your Honor.

MR. WEINBERGER: I'll rephrase.

MR. SWANSON: Objection, Your Honor.

MR. WEINBERGER: I'll rephrase.

13:23:29 THE COURT: Okay.

BY MR. WEINBERGER:

Q You found it to be an enlightening experience; right?

A Very much so.

Q Best tool you ever had?

13:23:40 **A** I would say it was the best tool I had for purposes of doctor shopping and profile reconstruction, yes.

Q Profile reconstruction not only with respect to the doctor's profile and prescribing patterns, but also with respect to the patient's profile and behavior; right?

13:24:09 **A** Yeah, that is.

Q Now, let's be clear, you as someone from the Ohio Board of Pharmacy, could use OARRS to run information about a particular prescriber; right?

A I'm not sure exactly in the beginning if we were able

13:24:31 to do that or just patients initially, but eventually we were able do it, yes.

Q Right. Something that the pharmacies could not do. They couldn't look at --

A No.

13:24:41 **Q** -- doctor profiles, they could only look at patient profiles; correct?

A Patient profiles specific to them.

Q Right.

A They didn't have that actual access at that time.

13:24:55 **Q** Right. So --

A That came after, I think, I retired.

Q Right. But you could see -- you could see from the -- from OARRS evidence of doctor shopping; right?

A Yeah, I could.

13:25:07 **Q** Cash payments versus insurance; right?

A I believe, yes.

Q The trilogy, you could see evidence of the prescribing and dispensing of the three drugs to a particular patient; right?

13:25:30 **A** If I was running that particular doctor or patient yes. This didn't jump up in my computer and say, hey, look at me. I had to enter stuff to find it.

Q I'm sorry, I. . . could -- but you could run a -- you could run a doctor's profile and figure out --

13:26:01 **A** Oh --

Q -- and figure out what the propensity was for the doctor to prescribe the three drugs in the trilogy to a number of patients; right?

A Yeah. At one time during OARRS established dates we

13:26:23 were able do that as agents and specialists, yes.

Q All right. And you could tell whether or not there was an early refill for a particular patient; right?

A Yeah. It would show patient specific, drug specific, dates dispensed, next date dispensed, so yes, the answer is

13:26:53 yes.

Q So you could actually tell from OARRS, from their OARRS report, if a prescription was legitimate or not. True?

MR. SWANSON: Objection.

13:27:06 THE COURT: Well, let go on the headphones.

(Proceedings at sidebar.)

MR. SWANSON: Your Honor, the objection is he's trying to get in expert testimony through a lay witness who is not a pharmacist. He's saying he wants to support 13:27:45 the work that Mr. Catizone did by suggesting through this witness you can identify a red flag just by looking at aggregate data.

MR. WEINBERGER: Your Honor, I didn't --

THE COURT: I'm not sure what he's doing.

13:27:56 MR. SWANSON: Well, I guess I'm not either. That's my best guess and that's the objection.

MR. WEINBERGER: Your Honor, that's a direct quote from his deposition testimony. It was such a good tool that he could determine from an OARRS report whether a 13:28:09 prescription was legitimate or not. I didn't just pull this out of the air.

MR. SWANSON: That's not the issue. I mean, just because he says something at a deposition doesn't mean it's admissible.

13:28:17 THE COURT: Well, if he used it as an

investigative tool and that's how he decided whether a prescription was legitimate, he can say, that's how I decided, I used OARRS -- I consulted OARRS.

I mean, so it sort of came out a little bit out of the 13:28:36 blue, but if this is somehow tied to --

If you can bring out, Mr. Weinberger, that when he was conducting an investigation he used OARRS and that's how he decided if a prescription was legitimate or not, then he can talk about what he did as an investigator.

13:28:57 MR. SWANSON: Correct, but it's not one could do this or one could do that --

THE COURT: It's what he did. All right. Okay.

MR. SWANSON: Yes. That's the objection, 13:29:02 correct.

THE COURT: Okay. That's fine. It's got to be couched in what he did as part of his job and then it's -- then it's permissible as opposed to just some -- some blanket use.

13:29:14 MR. SWANSON: Your Honor --

(In open court at 1:29 p.m.)

BY MR. WEINBERGER:

Q Mr. Pavlich, would you use OARRS to -- in the course of your investigation of prescribers or patients?

13:29:45 **A** Yes.

Q And when you got an OARRS report during the course of your investigation, you could actually tell from the report whether or not a prescription was legitimate or not. True?

A No, not all the time.

13:30:05 **Q** But sometimes --

A If it was altered, if it was written for 10 doses of oxycodone and a patient changed it to a hundred and the pharmacist didn't catch it, OARRS wouldn't catch it.

Q Right. We're not talking about that situation.

13:30:23 But there were situations when you could use OARRS and the data and information you got from OARRS to tell whether a prescription was legitimate or not; right?

A In certain situations, yes.

Q Okay.

13:30:38 **A** Not all.

Q Right. And if a prescription is determined to be not legitimate but was nonetheless dispensed, that could lead to diversion; right?

MR. SWANSON: Objection.

13:30:59 THE COURT: Sustained.

BY MR. WEINBERGER:

Q That would be evidence of diversion, wouldn't it?

MR. SWANSON: Objection.

THE COURT: Sustained.

13:31:09 BY MR. WEINBERGER:

Q So we've talked about the pharmacists at some point in time early in OARRS limitation in terms of not being able to see or look up the prescriber profiles to look for pattern prescribing or volume prescribing or things like that.

13:31:34 You recall a few minutes ago talking about that?

A Yes. The pharmacists didn't have electronic database like myself as an agent. They had other pharmacists would call them about things, but. . .

Q Right.

13:31:47 **A** Not electronic database.

Q Right. So -- but you did tell us earlier that at headquarters, there was data -- at the headquarters of these chain pharmacies there was data from the dispensing of opioids from every one of the stores owned by that chain;

13:32:12 right?

MR. SWANSON: Objection. Mischaracterizes what he said.

THE COURT: Overruled.

THE WITNESS: I'm pretty much guessing on that

13:32:22 because I never was in an HQ and saw that.

BY MR. WEINBERGER:

Q All right. Fair enough.

A I'm just make an assumption.

Q But we can agree that OARRS takes the dispensing data

13:32:37 for the chain pharmacies and can evaluate, or help people

evaluate the -- the prescribing habits of doctors and prescribers -- and other prescribers; right?

A I'm not sure as to the extent when a pharmacist in a store who has access to OARRS can see. I know an agent and a specialist could, but I'm not certain on what they could see because I had retired when they got access.

Q Okay. I'm sorry. I -- that was a bad question. Poorly phrased question.

You talked about earlier, from your perspective, that you could use -- that the dispensing data from the pharmacies went to OARRS, and from your perspective, you could use that dispensing data to look at the behavior of doctors and prescribers; right?

A Yes. If I punched in specific information, I could look at specific details.

Q For these large chain pharmacies, looking at their own dispensing data at their headquarters, do you know whether or not they could look at their own -- the prescribers whose prescriptions were filled across the country to look for the patterns of behavior of prescribers?

A I am not aware of what they could do with their systems.

Q Prior to 2011, did your inspections, your 2 and a half hour inspection once every year or two for a particular pharmacy, look for evidence that OARRS was checked by the

pharmacist?

A I don't recall when the pharmacists had access to OARRS, so I'm not certain if they had access when I was still working.

13:35:03 **Q** Okay. Are you aware of the fact that in 2011, in October of 2011, the Ohio Board of Pharmacy regulations were changed to make it mandatory that pharmacists check OARRS under certain circumstances?

Are you aware of that?

13:35:26 **A** October of 2011?

Q Yes, sir.

A That was probably 5 months before I retired. I don't recall that. Sorry.

Q So if it was -- just to -- stay with me for just a

13:35:44 minute. As Mr. Lanier would say, just track with me for a moment. Okay?

If it was mandatory under certain circumstances as of October of 2011 that a pharmacist check OARRS, did any of your inspections, between October of 2011 and March 1st,

13:36:07 2012, when you retired, include looking at records to see whether or not the pharmacists for these chains checked OARRS?

A Again, I don't recall when they had access, and I don't even think if they looked in the OARRS system that it

13:36:29 would reflect on something unless there's a paperwork that

was generated that they went into OARRS that I would see. I don't recall ever seeing paperwork like that.

Q Certainly when you did your inspection of the hard copies and these files at the individual pharmacies, you didn't see an OARRS report stapled to or appended to the script; right?

13:36:50

A I don't specifically recall, no.

Q Now, we talked about earlier that you -- that you knew Brian Joyce who was the pharmacy supervisor for the Trumbull stores for Walgreens; right?

13:37:13

A Yes. Correct.

Q Were you aware that Mr. Joyce served on the board of the Ohio Board of Pharmacy?

A Yes. When I was still there.

13:37:25

Q Um-hmm. And were you made aware by Mr. Joyce in your conversations with him that when the Ohio Board of Pharmacy made a proposal to make OARRS mandatory under certain circumstances, that Mr. Joyce, as a board member, opposed that change?

13:37:45

MR. SWANSON: Objection, Your Honor.

THE WITNESS: Can I answer?

THE COURT: Sustained.

MR. WEINBERGER: You cannot answer. The Judge sustained the objection.

13:38:01

THE WITNESS: I heard.

BY MR. WEINBERGER:

Q Did you ever -- did you ever have any conversations with Mr. Joyce about his being a board member of the Ohio Board of Pharmacy?

13:38:16 **A** Yeah, I'm sure I congratulated him.

Q Right. I'm sure you did.

And did you ever have a conversation with Mr. Joyce in which he expressed his feelings about OARRS, about the use of OARRS?

13:38:38 **A** Not that I recall.

Q Are you familiar with the term "blanket refusal to fill"?

A Yeah, I would say I heard of that phrase. Not one that I would use, but I've heard of it.

13:39:17 **Q** What do you understand blanket refusal to fill to mean?

A No matter what prescriptions from specific prescriber comes in, we don't fill it.

Q And you --

13:39:31 **A** Blanket.

Q And you were aware that as to some of the pharmacies in your district there were blanket refusals to fill with respect to certain prescribers?

A I can't think of specific ones, but I recall up in

13:39:49 Geauga County, yes.

Q All right. Just to sort of wrap things up, sir. As you sit here today, you have no specific knowledge of the volume of pills -- of opioid pills dispensed in Trumbull County or any of the other counties where you were in charge of inspecting pharmacies, you have no idea of the volumes of pills during your tenure; right?

A No, I have no knowledge.

MR. WEINBERGER: Thank you, Your Honor. I pass the witness.

THE COURT: Objection. Before we have redirect, if any of the jurors have questions, if you'd give them to Mr. Pitts and I'll give them to counsel.

Thank you.

(Brief pause in proceedings).

(Proceedings at sidebar.)

THE COURT: I don't have any of these questions.

MR. SWANSON: Oh, I'm sorry. Well, let me --

THE COURT: I mean, you can read them to me if there's a concern about, you know, what you can ask or you can't, well --

MR. WEINBERGER: I'm sorry, I can't hear.

Wait a minute. Okay. We can now. Sorry.

MR. SWANSON: Your Honor, I was just going to read -- I think they all look like they're okay questions.

THE COURT: All right.

MR. SWANSON: I was going to read the one that we think isn't.

THE COURT: All right. Which one are you concerned about?

13:44:40

MR. SWANSON: So there was a question, it says, with your expertise, do you believe the defendants were as a corporate responsible for --

THE COURT: Right. We're obviously not asking any question like that of any witness.

13:44:52

MR. SWANSON: Okay.

THE COURT: Maybe an expert, but certainly not with this witness.

MR. SWANSON: And I think that was the only one that we thought was not proper. But as I'm reading them, there are literally a dozen of them, so if I come up with another, I'll approach.

13:45:03

Is that okay?

THE COURT: That's fine. That's fine.

MR. SWANSON: Okay. And again, Mr. Swanson, you don't -- you're not required to ask them. I mean, it's -- that's not -- I give them to both counsel so that if you want to ask them, that's fine. If you think it's better with another witness, that's fine. If you think it's irrelevant, that's fine.

13:45:15

13:45:30

MR. SWANSON: Okay.

THE COURT: But I agree, if there's one that you're concerned about whether it's proper, this is the way to proceed.

13:45:38 MR. SWANSON: I appreciate that, Your Honor. I'll proceed in that manner.

THE COURT: Okay.

MR. SWANSON: Okay. Thank you.

(In open court at 1:45 p.m.)

13:45:44 REDIRECT EXAMINATION OF GEORGE P. PAVLICH

BY MR. SWANSON:

Q Hi, Mr. Pavlich.

A Hello.

Q I don't have a lot of follow-up for you, but we did

13:46:18 get a whole bunch of questions from the jurors. They're allowed to write down questions that they would like answered, and I'm going to go through and ask -- ask them to you. If you can answer them, that's terrific. If you think that for some reason you can't, you can just say, I don't

13:46:37 know the answer to that. It's all fair. Okay?

A Okay.

Q So first there's a question, out of the -- maybe I can put it on the. . .

There was a question, out of the chain versus

13:47:06 independent pharmacies, which ones were issued more

quote/unquote pink slips?

And I think that comes from your inspection report, the pink sheets.

A Well, obviously there's more chain pharmacies, so based on that alone, they probably got more pink sheets.

Q And when you say there are more chains, are you talking if you put all the individual -- or all the independents together, were there still more chains?

A I think so. There are more chain stores than there are independents, but. . . that's -- that's just a guess.

Q What about when a --

A Best I can say.

Q Sorry. I didn't mean to interrupt. Are you all right?

A What? Wait a minute.

My screen reduced. I didn't know what you were doing.

Q Sorry. I picked it up.

A There we go. There we go.

Q Let me ask you, instead of just the volume you're talking about as a percentage, so did the chains versus the independents at a store level tend to have more pink sheets?

Do you understand that distinction?

A More extensive pink sheets for violations, I would say independents.

Q Okay. The next is a question about audits.

It says, audits were only done if an investigation was opened?

A Yes, because that required a lot of work. I mean, you're covering everything that's purchased, dispensed, and in stock, and you're crunching all the numbers to come up with a zero balance accountability, and I didn't just do it to do it.

Q By the way, when it came to pink slips, or excuse me, pink sheets I guess they're called, did you issue pink sheets for anything from very egregious violations to violations that you felt were necessary that the pharmacy put their attention to but that weren't, you know, serious, there's, you know, potentially criminal activity going on here level?

A Yeah. If I saw a number of administrative things that were -- I'm viewing in the pharmacy, I would document it on a pink sheet and ask for a reply. It all depends. If there was just one thing, like a few scripts didn't have manual initials, no, I wouldn't issue a pink slip in that case.

Q Okay. The next question is, did any of your investigations ever require you to pull physical scripts from any of the defendants?

A Yeah, I pulled scripts from probably every pharmacy store in my geographic at one time or another for various reasons.

Q And, so, can you give us a reason why you might go into a chain pharmacy and ask for prescriptions?

A Most of the time it involved doctor shopping, patients going to multiple doctors and going to multiple pharmacies, and this is a lot of times before OARRS came into existence. I would manually have to search all this out. So every pharmacy at some time during my career with the Board of Pharmacy had me pull something out of there.

Q Would the pharmacists at Walgreens, Walmart, CVS, sometimes gives you a call and say, hey, we have some suspicions here based on this prescription, why don't you come down and then you'd give them the -- they'd give you the prescription, you'd pull that?

A Sure.

Q Here's a question: During your years as a field agent, from 1987 to 2012, did you notice a large increase in the dispensing of prescription opioids in your geographic area?

What year was it the highest?

A That's a good question.

Well. . . I would say the year it was the highest is when I did Overholt's Pharmacy. That was the most extensive dispensing I ever saw coming out of a pharmacy for specific patients. So I'll say that year, 2008 and '09.

Q Okay.

A '07. They had scripts from '07. So during that period probably. There was some other large things going on, but that one just jumps out at me.

That's a good question.

13:53:17 **Q** I had a question here from a juror that I had -- that was sort of in my mind too. When I was asking you about the inspections that you would perform at pharmacies and the things that you would do and the things that you would look at, I thought you had said -- and maybe I'm wrong -- but I

13:53:36 thought you had said you can see the dispensing policies for the stores.

Do you remember that?

A You know, I might have said that, and I might have seen the dispensing policies and training manuals. I mean,

13:53:50 in pharmacies, there is so much paperwork that they got to keep track of and books they have in there, sure, but for me to inspect them and look at them, I don't recall ever doing that.

Q Did you ever have discussions with the pharmacists or

13:54:05 the pharmacy leadership about what sort of policies they had in place regarding dispensing of controlled substances?

A I'm sure I engaged -- I'm sure I engaged pharmacists in a conversation about dispensing of controlled substances.

Q Okay. So the question which this juror asked is if

13:54:39 dispensing policies were not reviewed on a regular basis,

how could it be determined the pharmacy that were doing their jobs and/or our due diligence in dispensing of opioids?

A Regardless of what a policy or procedure or a corporate or an independent book says for a pharmacist to do, I mean, they could say fill everything, blanket prescriptions, from any doctor in any one, no questions asked. That's irrelevant to me. What was relevant to me was the drug laws of the State of Ohio, the law book, that had the federal, state, administrative, and criminal code in it. That's what I would look and make this determination. Their policy's irrelevant to me.

Q You were asked a question by Mr. Weinberger about when a patient would come in and the pharmacy would refuse to fill the prescription, they would give -- the pharmacist would give the prescription back to the patient.

Do you recall that?

A Yes.

Q And why was it that the pharmacist would give the prescription back to the patient?

A Well, corresponding responsibility to the prescribing of the medication. If they're not comfortable dispensing it, I never in my career would tell a pharmacist fill something if you don't feel good about it.

Q Yeah, and I appreciate that. I think my question

wasn't clear.

I was wondering why would the pharmacist give the prescription back to the -- back to the patient if the pharmacist had decided not to fill the prescription?

13:56:42 **A** Oh. Oh, I'm sorry. I went on a tandrum [sic] there.

They would give it back -- I think I testified a prescription issued by a prescriber to a patient is now the property of the patient. The patient brings it to the pharmacy. If they present it and it's not dispensed, it

13:57:03 remains as the property of the patient, not the pharmacy.

Q Yeah. And do you know if any of the chain pharmacies before handing the prescription back to the patient would make a copy of the prescription so they had a record that they would refuse to fill?

13:57:25 **A** Yeah, I was going to say that. I've had that happen, and then need call me. Some even kept the prescription, but, you know, a pharmacist doesn't want to get into a confrontation in the middle of the store. So a copy worked.

Q Yeah. So just to make sure that I'm clear in the way

13:57:46 I'm thinking about this, if a patient comes in to the pharmacist and gives the prescription to the pharmacist, and at least in my experience the pharmacist will then take it and go back and look at it in the pharmacy, and could the pharmacist copy that prescription, make a determination that

13:58:04 he or she wasn't going to fill that prescription, give the

original prescription back to the patient and maintain a file of the copy?

Was that, in your experience, something that happened?

MR. WEINBERGER: Objection, Your Honor.

13:58:16 THE COURT: Yeah.

MR. LANIER: Leading.

THE COURT: I'll sustain that.

BY MR. SWANSON:

Q Do you have any memory of any of the chain pharmacies keeping files of copies of prescriptions that they had refused to fill?

A Now that I don't recall, but I recall copies being made and given to me.

Q So you don't have a recollection of pharmacy keeping copies of prescriptions they had refused to fill?

13:58:50

MR. WEINBERGER: Objection, Your Honor. Asked and answered.

THE COURT: I'll allow that one question.

THE WITNESS: No, I don't recall of any files with prescriptions of that sort.

13:58:57

MR. WEINBERGER: I'll withdraw the objection, Your Honor.

BY MR. SWANSON:

Q I think this was -- at least part of this might have been asked by Mr. Weinberger, but did you do an inspection

13:59:15

at Overholt's Pharmacy every year? For how many years? How many pink sheets per inspection?

A I know I had not done an inspection at Overholt's Pharmacy for, oh, it was at least a year or two prior to when I went in there on the Dr. Franklin investigation. I was not aware the extent of what they were doing in there. I was -- I was pretty busy.

I would probably not be in pharmacies every year. It was just -- I mean, we had -- we had so many sites to inspect, not just pharmacies. You name it, nursing homes, fire stations, ambulance. We were busy. So I did the best I could.

And with Overholt's, yes, if I would have been in there every year, I might have spotted those prescriptions, but. . . good question.

And how many pink sheets per inspection? That would -- it would vary, you know. If I didn't see anything, no pink sheet was issued.

Q Okay. Is there a rule when writing a prescription that the number of pills be written in Roman numerals instead of the Number 3 or also write out in text the word three?

A Prescribers would write in various formats. I mean, there was the Latin, and the TID, BID. Yeah, there was different code formats for things to be written.

Non-pharmacists like me like the layman's way of writing it, longhand, 3, instead of Roman numerals or something. But as long as a pharmacist can decipher what's written, it was good to go.

14:01:42 **Q** Okay. The question here is -- it's a series of questions, and I'll just read them and let you answer.

How do you choose which pharmacies to inspect?

How many pharmacies were in your geographic area? Just an estimate -- let me just stop there. I guess that's

14:02:23 easier?

A Okay. I would choose pharmacies based on the last time I was in a pharmacy. So if I wasn't in a pharmacy for two years -- to do a full inspection, not just to run in, pull a script out or something, ask them a question about

14:02:45 something. We were supposed to do 50 pharmacies a year. I didn't always meet that. I was pretty busy.

How many pharmacies were in. . . I'm going to guess just pharmacies in my geographic for four counties, I'm guessing 150, maybe more, 180. I'm guessing.

14:03:16 **Q** And how many field agents like yourself covered those counties?

A Well, toward the end of my career I had four counties: Trumbull, Mahoning, Columbiana, and Jefferson County.

At the beginning of my career I went from the eastern

14:03:40 border on the northeast of Ohio, from Ashtabula on down to

Columbiana all the ways across to Wayne and Medina County, excluding Cleveland and Cuyahoga County and Lake County, I had everything else.

Q What about as far as --

14:04:01 **A** And that was a -- that was a lot of pharmacies.

Q It sounds like a lot.

What about when you got into the 2006, '7, '8, you know, more towards the end of your career, did you have -- it sounds like you had a smaller geographic area.

14:04:17 Did you have more help in conducting inspections?

A Well, I had less facilities to take care of. So, obviously, it was less of a burden to do those four counties versus 10 counties, obviously.

Q Did an inspection sheet get submitted somewhere for

14:04:46 each inspection?

A Yes. If an inspection was conducted in a pharmacy, a nursing home, a fire station, an EMS, there was an inspection sheet. If we went in there on our official capacity to look at regulatory things, a sheet would be

14:05:09 issued.

Q Yeah, and the last question on this form, if you wrote a note, something you wanted to improve but not write up -- and at least my interpretation is in a pink sheet -- how would you follow up to make sure there was this improvement

14:05:26 that you sought?

A If I saw something major, obviously I issued the pink sheet. If I saw something minor, I would note it on the inspection sheet, manually initial your prescriptions, and I would communicate to the pharmacist working that this is what I want addressed. And next time, if I was in the pharmacy, those inspection sheets were in the store, so I can always go back and look at those inspection sheets in a 3-year, 7-year recall. They maintained them in a file. And I would do that at times to see -- you know, I couldn't remember everything I noted, and I would go in there and look at them and say, hum. Then if I saw it again, then they'd get a pink.

Q Okay. Did you ever, during your routine inspections, look at any of the defendant -- defendants' pharmacists' dispensing computer for any of the fields? And it says regarding red flags.

Did you look at the computer systems in your inspections?

A You know, I didn't really go into the pharmacy, independent or chain pharmacy computers myself per se. I would ask the pharmacist or the technician to assist me. Because obviously I wasn't savvy with all these different software systems. And I don't recall any fields regarding red flags in the computer. I mean, there might have been. I -- I just don't recall.

Q So I want to make sure I'm understanding this. The -- it sounds like when you would do these inspections, you wouldn't go and sit down and start, you know, rooting around in the computer, but if you had questions or wanted to see the computer, was it available to you through the pharm tech or the pharmacists to see what they were doing with their dispensing software?

Was that an option for you you could look into?

A Oh, yeah. All I had to do was ask. I mean, if I asked, I received 99.9 percent of the time. There was very few occasions when someone would refuse to cooperate.

Q I don't doubt that, sir.

MR. SWANSON: I think, with that, those are all the questions that I have for you. I, again, appreciate your time in answering my questions.

And maybe, Your Honor, if we could take a quick sidebar.

THE COURT: Okay.

(Proceedings at sidebar.)

MR. SWANSON: Your Honor, just a couple of points on some questions.

THE COURT: Okay.

MR. SWANSON: We talked about the one that I obviously didn't read.

THE COURT: Right.

MR. SWANSON: There was one above it, it said, did a pharmacist ever ask him to contact corporate supervisors with regards to being forced to continue to dispense scripts for customers that might have possible red flags?

14:09:18

I don't think there was any testimony about anybody being forced to continue to fill, so I just didn't ask that question.

THE COURT: Right. There is -- he certainly gave no testimony about that, so I think you should probably let that sit.

14:09:28

What does the plaintiff think? I mean, there's been no testimony about it. It's coming out of the blue. Certainly not from this witness.

MR. WEINBERGER: I think it's a relevant question, but, you know, with this witness and where he might or might not go --

14:09:45

THE COURT: Well, that's the point. That's the point.

MR. WEINBERGER: I'm --

14:09:57

Mr. Swanson, maybe the only time you and I agree, so. . .

THE COURT: Okay. I agree. I agree. We'll let that one sit.

MR. SWANSON: And then there were two that

14:10:07

were specific to Walgreens that I didn't ask, and I wanted to make sure Mr. Weinberger knows, because there was a question, during your inspections, did you look over Walgreens' good faith dispensing forms? And he was gone -- he had retired by the time those came out, so I thought it would be misleading to ask him about those.

14:10:22

MR. WEINBERGER: I agree with the timing of that.

THE COURT: Yep. Yep.

14:10:30

MR. SWANSON: Two or two. I'm going for the clean sweep here.

He said, did Walgreens give you access to their refusal to fill folder when you did an inspection?

And when I asked him the question he said he wasn't

14:10:43

aware that those forms existed, so I thought it would be misleading to ask that question as well.

MR. WEINBERGER: Well, he was aware that they made copies, but he did testify that he was never shown the files that contained the refusal to fill scripts.

14:10:58

MR. SWANSON: Well, then the question's been answered, I guess.

THE COURT: Yeah. I mean, I suppose can could ask him -- I mean, maybe -- did he ever ask to see them --

MR. WEINBERGER: Right.

14:11:08

THE COURT: -- would be the relevant question,

not which -- someone could ask him that. I mean --

MR. WEINBERGER: Well, I'm going to ask him that.

THE COURT: But he could be -- someone could ask him, did you ever ask to see them, and then if he never asked, well, then he would never have been shown them. There would have been no reason to show him if he never asked. So I would --

MR. SWANSON: Okay.

THE COURT: If we're going do it, I would ask it that way.

MR. SWANSON: Okay. Can I just ask that last question, and then I'm done.

THE COURT: Sure.

(In open court at 2:11 p.m.)

BY MR. SWANSON:

Q Sorry, Mr. Pavlich. I have, I hope, just one more question.

A Okay.

Q When you were doing your inspections at Walgreens, did you ever ask to see their refusal to fill folders?

A No. I didn't even know they had them that I recall. I mean, I could have seen them, but I don't recall ever seeing that, anywhere.

Q Do you recall any circumstance at Walgreens where you

asked to see something that the pharmacist wouldn't let you see?

A Oh, no. Never.

Q Okay.

14:12:20 **A** Never happened.

MR. SWANSON: Thank you very much, sir.

I will ask -- see if my colleagues have anything, or Mr. Weinberger.

THE COURT: Okay. Well, let's first see if

14:12:29 any of the other two defendants have any -- any follow-up questions for this witness.

MS. FUMERTON: None for Walmart, sir.

MR. DELINSKY: Nothing for CVS, Your Honor.

THE COURT: Okey-doke.

14:12:43 Then you're up, Mr. Weinberger.

RECROSS-EXAMINATION OF GEORGE P. PAVLICH

BY MR. WEINBERGER:

Q Mr. Pavlich, you talked about -- when you were asked about the written policies of the pharmacies that -- and

14:13:05 whether or not you inspected and looked at those, you said, in my opinion, the policies are irrelevant. They have to follow the law books that are there.

I mean, I'm paraphrasing your question -- your answer; right?

14:13:19 **A** Right. Right. Right.

Q So you understand that in the pharmacy world, the pharmacists are employed by the pharmacies; right?

A Okay.

Q Just track with me for a minute here.

14:13:44 And so like any employer, the pharmacies issue -- might issue written policies on rules that the pharmacists should follow in dispensing controlled substances.

Understood?

A Okay.

14:14:08 **Q** And those are the policies that you never looked at; right?

A Not that I recall.

Q And so you didn't look at those policies to determine whether or not they conformed with your understanding of

14:14:23 either the federal Controlled Substances Act or the state regulations; right?

A I don't recall looking at those policies.

Q Okay. Now, just one more line of questioning regarding Overholt's.

14:14:40 Overholt's was closed down as a result of your investigation in 2008; right?

A Pretty much so, yes. It continued on until they -- they sold it to another independent, but the pharmacists, the three pharmacists working there lost their licenses.

14:14:59 **Q** Right. So presumably Dr. Franklin and others had

patients who had their prescriptions filled at the Overholt's Pharmacy and then at some point in time couldn't fill them there anymore; right?

A They couldn't fill them anywhere. I went everywhere and told everyone what was going on.

Q Well, did you have a list of the patients of Dr. Franklin's whose prescriptions were filled at Overholt's?

MR. SWANSON: Your Honor, this is beyond the scope of -- I just asked questions from the jurors.

THE COURT: Yeah. Overruled.

THE WITNESS: Repeat that question.

BY MR. WEINBERGER:

Q Did you have a list of the individuals, the patients of Dr. Franklin, who had their scripts filled at Overholt's before it was shut down?

A Yes, I did have a list.

Q And did you take that list of patients -- and how big was the list?

A If I recall correctly, I, working with two specialists from my office, set a number at 100. Then I broke it down to 50 of the worst. Then I broke it down to 15 of the extreme worst, and that's where I targeted the investigation.

Q And those 15 patients were responsible for or received

from Dr. Franklin how many prescriptions?

A They received a lot of doses of medication.

Q What -- in the whole investigation that you went through from 2006 until 2008, isn't it true that it involved about 15,000 prescriptions?

A I don't recall how many prescriptions were involved. There were a lot.

Q Well, does 15,000 sound right? I mean, I can pull your deposition up.

A Yeah. I'm -- I'm going to agree with you. There was a lot of prescriptions that were pulled, but I broke it down to 15 patients at the end for purposes of criminal and administrative hearings.

Q Okay.

MR. WEINBERGER: Thank you, Your Honor. That's all I have. Pass the witness.

THE COURT: Okay.

MR. DELINSKY: Your Honor, may I just ask one question?

THE COURT: Absolutely, Mr. Delinsky. Well, wait a minute. Hold it, no.

MR. WEINBERGER: That's recross.

THE COURT: Right. I think that's --

MR. DELINSKY: Okay. I was a follow-up to Mr. Weinberger's question, but that's fine, Your Honor.

THE COURT: I think -- I think we're concluded.

MR. DELINSKY: Fair enough.

THE COURT: Okay. Thank you very much, Mr. Pavlich. We appreciate your appearance, and enjoy the rest the day. You may be excused.

THE WITNESS: Thank you, Your Honor, I appreciate it.

THE COURT: Okay.

(Witness excused.)

THE COURT: Okay. Defendants may call their next witness, please.

MR. MAJORAS: Your Honor, John Majoras for Walmart.

The defendants call Dr. Robert Wailes. Dr. Wailes will be testifying as an expert witness. He is a pain management specialist. And he will be talking about the standard of care using opioids in treatment, its relationships between pharmacists and physicians, and he will have opinions about the red flag analysis that were previously offered by Mr. Catizone.

MR. SWANSON: Your Honor, if I may.

THE COURT: Okay. Thank you, Mr. Swanson.

Doctor, if you could raise your right hand, please.

Do you swear or affirm that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth under pain and penalty of perjury?

THE WITNESS: I do.

14:19:26 THE COURT: Okay. Thank you. And you can be seated, and if you will please remove your mask while you're testifying. Thank you.

MR. MAJORAS: Your Honor, if I may.

THE COURT: Yes, Mr. Majoras.

14:19:46 DIRECT EXAMINATION OF ROBERT E. WAILES, M.D.

BY MR. MAJORAS:

Q Good afternoon, folks.

Good afternoon, Dr. Wailes. As you know, my name is John Majoras. I'm one of the lawyers for Walmart, and what

14:19:56 I'd like you to do to start is if you would please introduce yourself briefly to the jury and tell them a little bit about yourself.

A My name is Bob Wailes. I'm a practicing pain medicine physician in California. I have a small medical practice of

14:20:12 six practitioners, of three PAs, and three doctors, and have been working in the field for 37 years.

Q Now, Dr. Wailes, what I'd like to do is spend some time talking about your background and essentially how you got to where you are today.

14:20:26 And in your work in this case, you have given us --

MR. MAJORAS: And, Mr. Pitts, if I could get the ELMO, please. Let me center this a little better.

BY MR. MAJORAS:

Q Dr. Pitts -- Dr. Pitts -- I was just giving Mr. Pitts a new title.

Dr. Wailes, would you agree that what I'm showing you on the screen right now is your CV, which is essentially your resume that you have compiled throughout your years in your field?

A Yes, it is.

Q Okay. I'd like to take you through that a little bit.

Before we do that, though, you had worked with me to put together some slides to aid you in your testimony; is that right?

A That's correct.

Q And would that help you explain what you're going to offer opinions on to the jury?

A Certainly would.

Q So let's just simply begin first with your education.

Please take us through that.

A I did my undergraduate work at UC Berkeley, and then went on to medical school at Wake Forrest University in North Carolina, and following that, went to my postgraduate work in San Diego, at -- basically a one-year internship, it was a flexible rotating internship, and then a residency in

anesthesia and pain management at UC San Diego.

Q And just so we're clear, when you say "UC," you mean the University of California school system; correct?

A Correct. Thank you.

14:22:07 **Q** Talk to me -- or please tell us a little bit about your training as it led to your specialty in pain medication.

A Well, back when I was in school -- and it was quite a while ago. I finished all this 37 years ago -- pain

14:22:23 management was a very new field. It was an emerging field, and it was an outgrowth an anesthesiology.

And anesthesia was famous for using different procedures, we do different injection procedures to numb up parts of the body, and so we're used to using needles. And

14:22:42 some of those same techniques apply to, like, cancer patients to maybe kill nerves. It also applies to spine injuries where you can inject maybe steroids on nerves in the spine. We're used to doing a lot of spinal injections. It also lended itself with medications.

14:22:58 Certainly opioids we use in the operating room every day, all day. We use opioids to anesthetize patients and make them have less pain, and we also manage their pain after surgery in the recovery room and in their immediate postoperative period.

14:23:16 And at that time, when I was a resident, there were

changes out there where there was much greater recognition -- this is in the '80s. It was actually the early '80s. There was more recognition about the undertreatment of pain, and so it was the natural outgrowth of anesthesia to get more involved in that since we had some of the tools. And I really enjoyed being able to do procedures as well as talking more with patients.

In general, anesthesia doesn't talk a lot with patients, and I was kind of a gregarious person, so for me it was kind of a good fit to have that combination of procedures and being able to talk with patients.

And then really for me the concept was being able to help patients. I know that sounds a little hokey, you know, doctors all in your med school interview you say you want to help patients, but what can really be better than to try to relieve pain. And so that combined with it was a brand new field, it was a challenge, it was fun because it was new, and no one else was really doing it much at that time. It was a brand new specialty, motivated me to get to going.

Q In looking back over the -- well, let me ask you first. How many years have you been in this field since you graduated?

A Since I finished, 37 years.

Q So looking back over your 37 years, how does that work out with what you anticipated when you first started?

A Well, I had no idea exactly what would transpire in the next few decades. And luckily, we made tremendous progress over those years, both procedurally with the procedures I do as well as medications.

14:24:54 So the field has really evolved over that long period of time, and it's been a fun ride. It's been really interesting. The technology and the pharmacology and what we've been able to do for patients has really improved over that time.

14:25:12 **Q** So if I can take you back to the beginning, could you please explain a bit more about your education specifically as it related to pain management?

A And so certainly in medical school you get some of this, not enough, I believe. Now they do more pain

14:25:31 management training in medical school in terms of our 4 years of curriculum that includes basic pharmacology, advanced pharmacology, all the biochemistry and everything else.

Then you get practical application exposure to pain

14:25:46 management training from all the different specialties you visit in school. Because most specialties have some aspect of pain management. They all prescribe medications and painkillers. Not all, but most prescribe pain medications and painkillers for all the surgical specialties, of course,

14:26:06 and most of the primary care specialties need to be

conversive in how to use pain management tools.

And then certainly as a resident we got deeply into the fine details of pharmacology regarding all the anesthesia drugs, of which, of course, opioids are at issue here. That was certainly one of the most common drugs we use every day in anesthesia, and then as well as other pharmacology, and then as well as the procedures. And so you learn how to do procedures throughout the entire training in anesthesiology, and that's a big part of my specialty now, is doing minor procedures.

That evolved over time. At first, you know, when you think about surgical anesthesia, it's just like spinal injections or perhaps epidurals for women in labor and so forth. That evolved to much more. When I was a resident, it was a new concept, but now very commonplace to put catheters, little tubes in the spinal canal. That's what an epidural catheter is for labor. But now we found that we can do the same thing for cancer. And so we put these tubes -- these small catheters in the spinal canal, but we put -- make them permanent. We tunnel them under the skin, so instead of just one day of labor, you can leave them in for the rest of their life in cancer patients and deliver medicine directly to the spine.

That was a huge kind of a transition point for me because that was so definitive and can make such a

difference in people's lives. That was very motivating for me to go into the field when I started learning that technique as a resident.

And then from that, after I've been in private practice, there's a number of other innovations that came around. And I shouldn't go into too much detail probably, but --

Q I think we'll cover those in some detail, Dr. Wailes. Let me just take you back so we can get you -- everyone can understand why you're able to be here today.

You're -- after the training that you took and the school that you went through, your internships, you become a licensed doctor; is that correct?

A That's correct.

MR. SWANSON: And then perhaps, Mr. Ferry, if he could put the slides up, please.

Everyone apparently can see it but me. I'm sorry.

Oh, here we go. Let's go past. I think the jury can see Dr. Wailes in person.

BY MR. SWANSON:

Q So, Dr. Wailes, I'd like to talk to you a little bit about some of the things once you became a practicing physician.

Are you board-certified?

A Yes, I am.

Q And what does that mean, and who certifies you?

A What it means is -- to be board-certified means you have to take a special -- special training and have special background threshold training, like a residency and so forth, to qualify to take testing, and then you take testing to become certified. And they're usually one or two-day tests and very difficult and complicated, and the question is who is my certified by, the American Board of Pain Medicine. I'm certified by the American Board of Anesthesiology, and both -- I have a board-certification in anesthesiology, and then I have what's called subspecialty certification in pain medicine.

Q And when you say a subspecialty, what do you mean?

A That's -- they look at it as anesthesia is a specialist, and then I'm a subspecialty, which means a sub -- a fraction of an anesthesiologist, just a part of the specialty who specializes specifically in pain management. So there has to be separate testing and certification in that to prove my abilities.

Q In terms of your certification, do you have to maintain that in certain ways?

A Yes, I do.

Q How do you do that?

A For the American Board of Anesthesiology certification, specialty certification, I have to be tested

at a minimum of every 10 years to make sure that we're up to date and current with our specialty.

Q And are you currently certified still as a pain management doctor?

14:30:39 **A** Yes, I am.

Q We've heard quite a bit about the DEA during this case already. So are you a DEA registered doctor -- or I'm sorry -- DEA licensed doctor?

A Yes, I am.

14:30:49 **Q** And how long have you been with that registration?

A That's been since 1982.

Q Earlier you talked about the field that you're in being relative new, at least when you started.

Do you know when board-certification first became

14:31:04 available for pain management specialists?

A It was in the early '90s. It -- I believe it was in the early '90s, late '80s or early '90s is when it first became available.

Q And then I'd like to turn a bit.

14:31:24 You are a practicing doctor; is that correct?

A That's correct.

Q And by that, what do we mean?

A That means I see patients for a living.

Q How long have you been doing that?

14:31:31 **A** For 37 years, ever since I finished my residency.

Q And is that primarily what you do on a day-to-day basis as a practicing physician?

A Well, it's a combination of things. I also oversee -- we have three PAs in our practice, so there's medical supervision of that, and at my age now, I do a lot of administrative work and oversight work in our practice as well.

Q And as we can see in our slide, there's a reference to the Pacific Pain Medicine Consultants.

What is that?

A That's the name of my medical group.

Q And by medical group, that's the organization you just described with the PAs and the -- other doctors?

A That's my practice of six providers, three doctors, and three PAs, yes.

Q And who uses your practice? Who comes to you?

A Well, we see all kinds of patients. We're in north San Diego County, and we mostly get referrals, but we also take patients on direct referral and coming in to see me on their own volition. So we see all kinds of patients from all kinds of different sources. So it's a pretty wide variety.

Q And I'm sorry if I didn't hear this, but when did the Pacific Pain Medicine Consultants practice start?

A That started in 1985. I think it was the year

after -- year after I started private practice, we incorporated.

Q And in addition to the work that you've done with that organization, the Pacific Pain Medicine Consultants, what other clinical work have you done in your career?

A I --

Q I'm going to jog your memory. Have you been involved with the Scripps Hospital?

A Oh, well, it's still the same practice.

Q I'm sorry.

A Yeah. That's -- my Pacific Pain Medicine Consultants is the name of our group and our company. I've worked at a different locations. For example, we have two offices. I've also had -- I've been on the medical staffs of a couple local hospitals, one of those is Scripps Hospital, which is a very well-known private institution in San Diego County, as well as Tri-City Medical Center.

So as part of the pain management practice, we're not hired by hospitals. In California, they don't hire doctors directly. It's a little bit different in other states, but we work as consultants. So if there's patients in the hospital that need pain management services, our specialty, they would call us up, and we would go in and see the patient and do consultation and sometimes procedures and medication management.

Q And can you tell us about the work you've done with the Pacific Surgery Center during your career?

A Again, part of -- a big part of my specialty is doing procedures. It's not just medication management and patient management in the clinic. Part of what we do are different procedures, a lot of different injection procedures in the spine. We do -- again, we kill nerves. We also do different implants where we actually insert different devices in the body, and those need to be done at a surgery center with a sterile environment and sterile clean conditions and frequently with anesthesiologist who is taking care of the patient while I'm doing the work with the procedure.

And I created -- the Pacific Surgery Center was something that I started in 1990 to create a good environment for my pain patients.

Q So when talking about the surgery and the surgical procedures that you perform there, do those all relate to pain management?

A Correct. This particular surgery center is just exclusively pain management. Most surgery centers you may have been exposed to, they usually see orthopedics and OB/GYN and other specialties, but this is just a single specialty surgery center for us.

Q Okay. I'd like to talk to you now a little bit about

some of the medical associations that you've been involved with. And if we could go to our next slide.

The first is the American Medical Association?

Tell us about your work with the AMA.

14:35:38 **A** So I've been a member of the AMA through I'm sure most of my career, but I got to be more intimately involved with the AMA working with the American Academy of Pain Medicine. That's an organization -- a professional service organization of just pain specialists, and they needed

14:36:01 representation at the AMA, and to make a long story short, I became first the alternate delegate and then delegate over the last 10 years or so and have really enjoyed my liaison work there.

So what that means is I go to their meetings. They

14:36:20 have meetings twice a year, the house of delegates is what they're called, and that's where they establish policy.

The AMA is the largest physician organization in the United States and their influence is significant. And so it's important to have pain management representation there

14:36:39 to discuss some of the vital issues that come up in regular meetings.

Q And how long have you been a delegate with the AMA?

A Again, alternate and delegate for 10 years.

Q Give us some sense. How -- when we talk about the

14:36:52 delegation or the group that you're in, how big is that?

A It's huge. It's about 800 doctors, not counting the alternates. It's a huge organization and gathering for the conventions. And they have representatives from all the specialties and they also have geographic representation, but it's a large, very representative group.

Q And so those are the delegates. Do you know how large the American Medical Association is in terms of doctor members?

A You know, I'm not sure of the exact size. I apologize, I don't know the numbers exactly. It's not as member -- many members as we'd like. We always want more members.

Q You had mentioned one of the ways you got involved with the AMA is through your work with the pain management medical -- I'm sorry -- the American Academy of Pain Medicine, which is at the bottom of our screen.

Tell us more about that, please.

A And so every specialty has their own organizations. And this is probably the preeminent organization within pain medicine. There are others, and it's been my pleasure to attend many of their meetings and educational sessions, and most of these professional service organizations provide a lot of educational services, so people within the field stay up to date and are current in what's going on in the specialty. It's hard.

In medicine, that's one of the real challenges, and that's actually one of the reasons why I went into it, is that you don't get bored. There's always changes. You have to continue continuing medical education, and, in fact, it's mandated for licensure. You have to have many hours on a regular basis every year, but it's part the fun. And I really enjoy and have enjoyed for -- since the '90 attending the meetings for the American Academy of Pain Medicine.

And then, as time went on, I got more involved in the leadership and have been on for the last 8 years on the board of directors for the American Academy of Pain Medicine.

Q And can you just briefly tell us what it means to be on the board of directors of that organization?

A So, that's the leadership of the organization. And it's the board that decides and oversees the functions. And so within that board, we make assignments and oversee the educational sessions that come up. We oversee other services we may want to provide the membership. We have a journal and we have to oversee the administration and the work involved in the journal. It's a peer reviewed journal, which means that there's a lot of physician time spent reviewing articles before they're admitted to the journal.

Anyway, there's a lot of work within the specialty that the board of directors has to address.

Q In the last -- last item we have on this slide is your work with the Medical Board of California.

Tell us what that is.

A So the Medical Board of California is very similar to the Medical Board of Ohio. And this is the board that is tasked with the licensure and -- how should I say, the enforcement of the medical regulations and laws for physicians. And so you go through the medical board to get a license. And then you also pay attention to the medical board. They have certain mandates. They have a ton of different regulations for the practice of medicine. Again, very similar in both states.

Every state has a medical board, and as part of the regulatory function of the board, they do investigations into physicians. That's one of their really important functions. And if there's complaints of any type, it can come from patients, pharmacists, it can come from law enforcement. If you get a felony, it automatically goes to the medical board. A lot of different types of complaints go to the medical board.

And then -- I probably shouldn't go into too much detail, but they investigate the complaint of an individual physician, and if rises to the level where it requires a doctor to review the case, then they have specialists like myself who review the case. And so I review the case in

great detail and make -- usually come to conclusions that I forward to the medical board regarding the standard of care. That's what we look at. We look at was the physician in question practicing within the standard of care.

14:41:28 **Q** Now, how do you as a reviewer, an expert reviewer for the Medical Board of California, how do you go about performing that function?

A To make a long story short, it's a very long and tedious function. What they need to do is forward all the

14:41:44 medical records associated with the complaint, and typically medical records tend to be very large and very thorough. This would include all the pharmacy records, all laboratory records, the X-ray records, all doctors' notes, hopefully in electronic form, but sometimes written, which is really

14:42:08 hard, and you have to review those notes, and you have to review the issues that are brought up by the medical board.

They'll have a reason for the complaint. It may be, you know, any number of things. It could be documentation. It could be bad outcomes. It could be personality oriented.

14:42:26 There could be a number of different things that the board might be investigating, and I would have to go through and review the case and make some judgment on the -- on how that individual practitioner does compared to the standard of care.

14:42:42 **Q** In your role as a reviewer, are you looking primarily

at cases that involve pain management issues?

A Yes, that's absolutely true.

Q And I looked down in my slide, and I skipped over one that I don't want to miss.

14:42:55 You are actually the president of the California Medical Association; is that correct?

A I am. Yes, I am.

Q When did you become the president of that organization?

14:43:02 **A** Last Saturday night.

Q And have you accomplished a lot in your 4 days? I won't -- I'll withdraw that question.

Give us -- could you talk to us about what the California Medical Association does and maybe contrast that

14:43:19 a bit with the AMA, the nationwide American Medical Association?

A Okay. The California Medical Association, like Ohio, is an association of physicians within the state, and we do a number of different functions.

14:43:35 Our mission statement covers the public health, the science and art of medicine, and also social equity and justice. And so a good example is just kind of the things we did last year, we dealt intimately with creating policy for the governor of California, working directly with him

14:43:55 and his associates in the Department of Human Health and

also the public health departments on the whole COVID issue as well vaccine rollouts.

We have a public health arm. We have -- part of the CMA actually administers scholarships for doctors going to underserved areas. We have a loan forgiveness program for doctors who are trained in lower income areas and areas of need. We're trying to do our best to improve the maldistribution of doctors and caretakers.

We do many other things. We help individual doctors' offices with administrative things like electronic medical records and so forth.

We also do a lot of advocacy work. If there's certain issues, and certainly a lot of the vaccine issues required legislation and a lot of the public health issues require legislation, so we're very active in that field as well.

Most medical issues, many of them come before the legislature, so we spend a lot of time there. And also we deal with the medical board and their rules and regulation and so forth.

14:45:13 **Q** So as you think about these associations and boards that you've been a part of, are these volunteer organizations or are you getting paid for those roles?

A Basically, they're all volunteer with the exception of the California Medical Association. It's been volunteer up until just a few years ago, and I've risen to a level of

leadership where they have a stipend that goes along with my work at the California Medical -- everything else is all volunteer.

Q What are the stipends that you receive from the California Medical Association?

A Yeah. It was, I think, $50,000 as chairman of the board for two years. The year before that it was 35,000, and for president-elect, this last 12 months prior to Saturday night, I was president-elect and that was 75,000, and then for CMA president, which is a huge commitment of time, it's 150,000.

Q So if you look at the time commitment you have to spend now with the California Medical Association versus your practice, how does that work out?

A It will take a tremendous amount of time. It's estimated -- and every year is different. Being president, there's different issues every year and stuff, but it will probably take approximately anywhere between a fourth -- 25 to 50 percent of my time.

Q And if --

MR. MAJORAS: Mr. Pitts, if I can go back to the ELMO.

Thank you.

Q Dr. Wailes, the last thing I want to talk to you about on your CV are research projects, and we see that on the

screen in front of us. And without going through each of those, could you tell us, generally, what your involvement has been in research projects?

A I have done some research. I'm, again, mostly just patient care has been my emphasis and my practice. But over the many years we have done some projects. Most of them are related to procedures and devices. Anywhere where you see implant or catheter, those are different devices that we're testing out. I've really enjoyed my time with research, though, because it's -- patients really like to be involved in research, and it's very interesting work.

Q And you talked about we sometimes in your description. Who are you working with on these research projects?

A So primarily it's my office, but the way these research projects -- I think every one of these is, I'm just an investigator. I'm not -- I haven't led any specific research projects myself as the primary investigator.

Most research projects like this are multicenter research projects, so they want to get as many as patients as they can, and the way they do is they try to recruit as many medical practices or centers so they can build up a large number of patients. And so, again, I'm not academic like a professor. I'm kind of a worker bee, and so -- but they would come to me because we have a large patient population that they would be interested in and I would be

involved as an investigator.

MR. MAJORAS: Thank you, Mr. Pitts, and if we can go back to our slides.

BY MR. MAJORAS:

14:48:25 **Q** I want to talk a little bit more -- be more specific in our discussion about what a pain management specialist does. And you've helped me with this slide.

Can you take us through -- the first you talk -- you point out is patients with high complexity needs.

14:48:40 What does that mean?

A Well, in our specialty, we deal with the challenges that are not easily taken care of. Most pain management problems you probably all realize are taken care of by primary care doctors.

14:48:54 **Q** What's the difference? What's a primary care doctor versus like what you do?

A So a primary care doctor is a general practice doctor or an internist or someone you go to see in an urgent care or express care, emergency room, someone who you see

14:49:10 initially and who takes care of basic problems.

A specialist like myself are ones that take care of more complicated problems. And so I would be getting -- it says high complexity needs. I see the patients that the primary care doctor is challenged by, they're not happy with

14:49:28 how that patient is doing for any number of reasons. It

might be based on the severity of their pain and they can't function. It might -- meaning that they need help with medication management. It may be the nature of the problem. But we deal with the most challenging patients.

14:49:45 So, again, routine patients, most -- hopefully, I always tell me when they ask me what I do, I say I'm a pain management doctor, and I say I hope you never need me. I hope you don't, because it would imply that there's something pretty serious going on, and not just something

14:50:01 routine that can be taken care of at a regular office.

Q And then you have here that you evaluate and diagnose causes of patients' pain.

I think that makes some sense, but if you could explain that a bit.

14:50:16 **A** Sure. Sometimes it's not perfectly clear what's going on with a patient. Statistically the most common diagnosis area that I deal with is back problems, and all of us know, 80 percent of Americans have problems with their back at some point. And I'm specialized in evaluating the exact

14:50:32 cause of the back problem. Sometimes it's just muscle spasm. Frequently it's much more advanced than that. When the back problem doesn't get better, that's when they send patients to me, and it's part of my specialty to diagnose and evaluate through different imaging, test, MRIs, and so

14:50:50 forth, as well as physical examination, history, and all of

that that goes toward diagnosing the problem so I can have a very specific treatment plan hopefully designed to alleviate their symptoms or cure their problem, if possible.

Q I know it can be difficult to describe what pain feels like, but can you give the jury a little bit of background on how severe the pain is that -- in the patients that you're generally treating?

A Yeah. I guess one look at our waiting room before COVID, now we don't have very many patients in our waiting room, but you would extent of the type of patients we deal with. Many are in wheelchairs. Many have canes. There's many severe problems that I deal with on a regular basis. Multiple sclerosis. Spine injuries. Brain injuries after auto accidents. Broken bones that never healed up correctly despite good orthopedic surgery. People that have had prior back surgeries is a really common patient for me.

And these are not patients that live a normal life. These are patients that are suffering and in miserable pain and need help. They're not able to get around. It's like I say, that's why they need wheelchairs or canes. Getting to the doctor's office for some of my patients is the only activity they do getting out of the house on a monthly basis. So I deal with the most complex and uncomfortable patients routinely.

Q As we look down the list in front of us, there's some

discussion about some of the things you do to treat the pain that you see in your patients.

What do you mean by procedural interventions?

A I was alluding to some of that earlier. And so I do a number of different procedures, like injections into the spine of different medicines trying to alleviate injured nerves. Obviously for back pain, herniated disks and things like that, that can be helpful. For severe arthritis we do procedures, and sometimes we treat the nerves that go to the specific joint.

We use other things that most people are not familiar with but are common in our specialty, spinal cord stimulation. It's a fancy name for inserting a tiny wire in the spinal canal and using electricity to block the pain instead of medicines. We also insert pumps underneath the skin that deliver medicine directly to the spine. And so there's different techniques that we use with procedures to try to help people manage their pain.

Q Are these procedures that you described, are those ones that you actually perform?

A Yes, I do those procedures.

Q You also have here that opioids are one of the tools you have to manage pain.

Tell us about that.

A Well, the reason why I phrase it like that is, opioids

is just one of the tools that we have. Now, obviously, in many cases, we are using opioids because it's a painkiller. I mean, it's rather intuitive that if you have pain that's not resolved with other ways, that's one of the tools we use.

14:53:58

But certainly we try many other things first. I mean, you would always want to use easier techniques. You would want to use physical therapy, you'd want to use exercise. We have psychological -- like, use -- we refer to psychology a lot. There's psychological techniques that can be very helpful. But medication management is part and parcel with our practice every day, of course, because our patients are complicated. Many of them by the time they've seen me have already exhausted, if you will, the less invasive, easier techniques, and then we use opioids as one of our tools in treating our patients.

14:54:11

14:54:28

Q And could you tell us a little bit more, perhaps with examples, obviously not using any names, we don't want to have any personal information here, but can you give us examples of how you might distinguish in terms of your treatment whether opioids or some other type of procedure is the appropriate method of treatment?

14:54:42

A Yeah. Good question, and complicated.

And what it deals with is kind of the real issues in our specialty of how do you best optimally treat a patient.

14:54:59

And it has to do with the type of pain they have. Some types of pain respond better with opioids or other medications. Frequently the types of pain, there may be nerve pain or may be muscle pain, there's different types of pain, may respond better to physical therapy and exercise. Sometimes there's no good options.

I deal with patients, like, with spinal cord injuries that have scar tissue on their spinal cord, and it can be devastating. It can cause some paralysis. It can cause loss of urinary function and bladder function and severe pain in their lower extremities. And you do the best you can. You see what's available. You try the easier things first, and opioids are one of those tools that you go to when necessary, and sometimes it's the best tool to treat severe refractory pain when you've exhausted all the other easier choices.

Q What's refractory pain?

A Refractory, I'm sorry.

Q What is that?

A Refractory pain is pain that's not resolved with anything else. It means that you've tried the easy stuff and nothing else works, and you still have pain and you're looking for solutions.

Again, for me, this is a big part of our practice, is that patients come to us this way and you need to do your

best. It's a severe problem. You want to do the best to make sure that they can have some quality of life to try to at least be able to get up for meals or at least try to help themselves around the house. But many of my patients don't do chores or can't really get outside very much, and so you do the best you can to increase their function.

14:56:44

Q When you determine that an opioid treatment is the appropriate method of treating a patient, do you provide the patients with information about opioids and what they can do?

14:57:01

A Oh, yes. It's a big part of our practice is informing consent and discussions about the pros and cons, the risks, the benefits of opioid therapy. We're very thorough about that, especially as a specialist. But most doctors now are so aware of the pros and cons with opioids, it's been in our continuing medical education so much in the last 10, 20 years that really most doctors are very familiar with the risks and benefits.

14:57:20

And so, yes, we even have opioid agreements where we detail out exactly, well, pros and cons, risks and benefits. But managing expectations is also a big part of what we do. Managing expectations, I think, is really critical. And part of that managing expectations and current day use of opioids is letting them know that it's not going to be perfect pain relief. It's not going to be a hundred percent

14:57:38

14:57:59

pain relief, but we want to help them to the extent that it will increase their activities, it will increase their functional level. And that's kind of a change over time. That's evolved over time. But that's part of the expectations that we try to work with.

Q In addition to talking to your patients about opioids, do you do anything to mitigate the potential that the patient will run into use problems with the opioids?

A That's a whole big subject of which I think we'll talk more about later probably and -- but the answer to that question is before we even consider opioids, you go through a significant screening process. And this involves a number of different things. And so in the decision-making that goes toward starting an opioid or continuing an opioid, for that matter, is, first, the patient history and a thorough knowledge of their family history regarding drugs of abuse and so forth and addiction.

You also deal with their history and any red flags. You do a very thorough history regarding a number of issues that we know are risk factors for misuse.

And then furthermore, we also get laboratory testing on all of our patients on opioids. From the first visit on, we do urinary drug testing.

We also check the PDMP. That's the prescription medicine database that every state has. It's OARRS in Ohio.

So it's a -- it monitors the -- what prescriptions have been given to the patient by every doctor. So it's a specific database so I know the dose, frequency, and who gave them controlled substances over the last year, or longer if I need it, but -- so that's important information.

So a lot of investigation and work goes into knowing their risk factors and so forth before we would start the use of opioids.

Q The last two things I'd like to cover on this slide, the point toward the bottom, behavioral interventions.

You may have mentioned some of those already, but what do you mean by that in terms of your toolkit in treating patients?

A Yeah. The ideal type of chronic pain management -- and again, this doesn't apply to acute pain -- but for chronic pain management that's long-term in duration, behavioral interventions are really helpful. And what that means is referral to primarily psychology, but occasionally psychology for two really good reasons.

One reason is that psychologists have many tools to specifically help with pain management. It's everything from self-hypnosis to biofeedback to meditation, relax techniques, behavioral cognitive therapy, it's a fancy name for a technique to help have patients tolerate their pain better on a day-to-day basis.

The second reason to refer for behavioral interventions is that a high percentage of my patients suffer from depression and anxiety and other side effects of their chronic pain. It's part of the disability that goes with pain and suffering. It affects every aspect of your life. And so behavioral interventions can be helpful with that as well.

Q And lastly on this slide in front of the jury, you wanted me to include the -- what's in the blue box at the bottom, compensation is not linked to opioid prescribing.

Could you tell me what you mean by that and why you wanted to make that point?

A I put that in there because I think there might be a misunderstanding, and again, everyone may or may not have a friend or relative who is a provider or a physician, but doctors don't get paid for writing prescriptions. There's no kickback or anything. I mean, we get paid for our cognitive services or procedures. There's no reimbursement. There's no -- there's no incentive financially to prescribe medicines. In fact, there's a greater financial incentive to do procedures because procedures are more lucrative. That's why surgeons get blamed for doing too many procedures sometimes.

But just as a way of understanding, we get paid for office visits based basically on the length and complexity.

It's easier for us not to prescribe medications, because every time we prescribe a medication, there's a lot more documentation and stuff that's required.

But just to make that clear, because I know it's confusing for some if you're not involved in medical billing, I wouldn't expect you to know that, but if you see your explanation of benefits that come across your desk, you'll see that there's never a specific bill -- the medications are all typically not a hundred percent, but typically all dispensed in a pharmacy.

MR. MAJORAS: Your Honor, this would be an appropriate place.

THE COURT: I was going to suggest that. Thank you, Mr. Majoras.

All right, ladies and gentlemen, we'll take our afternoon break. Usual admonitions apply. We'll pick up in 15 minutes with more testimony from Dr. Wailes.

And you can step down and also take a break, Doctor.

(Jury excused from courtroom.)

(Recess was taken from 3:03 p.m. till 3:20 p.m.)

COURTROOM DEPUTY: All rise.

(Jury returned to courtroom at 3:23 p.m.)

THE COURT: Okay. Please be seated.

Doctor, you're still under oath.

And, Mr. Majoras, you may continue, please.

MR. MAJORAS: Thank you, Your Honor.

Good afternoon, folks.

Good afternoon, Dr. Wailes.

BY MR. MAJORAS

15:23:48 **Q** I'd like to ask you in the period of time in which you've been practicing as a pain management specialist, have you had the opportunity to interact with pharmacists?

A I have. On a regular basis, I have.

Q Why is that?

15:24:05 **A** In the course of a regular practice, pharmacists have an important rule, and they evaluate my prescriptions to make sure they're valid, to make sure they're -- there's no fraud, to make sure that there's no significant drug interactions or allergies, and I get calls occasionally to

15:24:25 make sure that the information I wrote on my prescription was valid.

Q And what's your reaction to calls like that?

A Well, it's certainly understandable, and I actually appreciate it. Historically, another reason why I used to

15:24:41 get calls were they would say a patient came in here with a prescription from you and it doesn't look like your signature. So they would be helpful. They would be helpful for fraud, and I always appreciate calls like that.

Pharmacists have the patient's best interest in mind,

15:24:59 and so I usually appreciate seeing what their concerns are.

Q Do you look at pharmacists as someone who can give a second opinion on your patients?

A No. No. That's -- that's not part of their role. They don't have the medical training or diagnostic tools and medical decision making that physicians have, and so I don't see that as part of their role.

Q Okay. We'll talk about that in a little more detail, but before we do, you mentioned that you have occasionally been involved in administrative proceedings before the California Medical Board.

Have you ever testified in a case like this with all of this in front of us?

A I have testified -- for the medical board you're asking?

Q In any respect.

A For medical/legal cases?

Q Yes.

A Yes. I have a total of three cases over my career where I've testified in court.

Q Is serving as an expert witness a substantial part of your professional practice?

A No. It's not at all.

Q And we've had a number of experts who have come here and spoken to the jury about their background and their opinions and have talked about their compensation that

they're being compensated for the time this they spent.

Is that the same with you as well?

A I'm sorry, I didn't understand the question.

Q I'm sorry. Sometimes I go too quickly on the end and the court reporter is laughing because she tells me that all the time, so I'll try to slow down.

I think I started with, we've had a number of experts who have testified and have been compensated for their time.

Are you being compensated for the time that you have spent on this case?

A Yes.

Q And do you know what your hourly rate is?

A I believe I do. I believe my hourly rate for review and consultation is 729. For deposition it's 1,275. For trial testimony it's 1,395, I believe.

Q And in terms of the work that you've done in this case, could you give us -- give the jury some understanding, you know, once we contacted you and asked you to take a look at it, could you explain the type of work you've done to date?

A Well, first, I was given a lot of information, and so I've reviewed testimony -- I've reviewed depositions, expert reports, different documents that were forwarded to me and also consulted with attorneys regarding the issues involved. So it's been many, many hours of work.

Q And in terms of the material you reviewed of other experts, what have you done?

A I've reviewed depositions and other expert reports.

Q And one of the opinions I'm going to ask you about relates to Mr. Catizone.

15:27:50

You understand he was one of the plaintiffs' experts in this case?

A Yes, I do.

Q And you've read his report; correct?

15:27:57 **A** Yes, I have.

Q Now, you haven't been able to see his testimony, but as I ask questions about him, I'd like you to assume that he testified consistently with the report you've seen.

Can you do that?

15:28:08 **A** Yes, I can.

Q All right. And in terms of your final product, aside from testifying here today, you also wrote a report; right?

A Yes, I did.

Q It was about 50 pages, single-spaced?

15:28:20 **A** Yes.

Q And in that report you explained the opinions that you've reached in this case?

A Correct.

Q And are you prepared to offer those opinions today?

15:28:28 **A** Yes, I am.

Q In terms of the total amount of time that you've spent in this case and looking as what you estimate as your total compensation for this case, it's a little over $201,000; correct?

15:28:44 **A** That's correct.

Q Sir, do you consider yourself to be an expert in the field of pain management and the prescribing of opioids?

A Yes, I do.

Q And you are here today to share with the jury your

15:28:57 opinions on the evolving treatment of pain; is that right?

A Yes.

Q You're also going to offer your opinions on the appropriate use of opioids; is that correct?

A Yes.

15:29:06 **Q** And that's based on your experience as well as your certifications and background work you've done as a pain specialist?

A Yes.

Q I'm sorry, pain management specialist.

15:29:18 **A** Yes.

Q Yes. As well as being an anesthesiologist?

A Correct.

Q And I just mentioned the work you did with respect to Mr. Catizone, which we'll hear about.

15:29:31 In doing so, in asking you your opinions, I'm going to

ask you to be very carefully in your responses and ask you to only provide opinions about which you have a reasonable degree of professional certainty for someone in your field and with your level of experience.

15:29:46 Can you do that for us?

A Yes, I can.

Q And so if you are offering opinions, it will be based on your experience and the 37 years that you have spent in this specialty.

15:29:56 Do you understand that?

A Yes, I do.

Q And are you prepared to offer those opinions?

A I am.

Q Let's go through some of them.

15:30:03 One of the -- one of the things you mentioned earlier, and we've heard a little bit about in this case is, you talked about chronic pain and then there's also acute pain.

And if we could go back to our slide. We're going to start on slide 5.

15:30:23 Dr. Wailes, can you tell us about the difference between chronic and acute pain and treatment issues with respect to those?

A Yes. Most people are familiar with acute pain. That's the most common thing physicians see, and it's pain

15:30:35 of -- usually from a trauma or a surgery or a procedure. It

can be from any number of circumstances. It can be kidney stones. It can be sickle cell. And these types of pain problems typically get better within days, sometimes weeks. And that would be acute pain. That's what most of the public are familiar with.

15:30:57

Chronic pain is different. That's usually of three or more months duration, and the more nuanced definition would say that chronic pain is pain that persists beyond the time of expected healing.

15:31:12

So, for example, after surgery, you may have ongoing pain despite you've -- looks like you've healed from your wounds, but there may be nerve injuries or other injuries that don't heal that you can't necessarily see even, but persist. So that would be chronic pain.

15:31:30

Q We've had some testimony in this case about chronic being -- equating to a certain number of days or months.

How do you look at it?

A There's no technically right or wrong answer there.

Again, chronic used to be thought to be over

15:31:45

six months in general and now we say probably over three months in general, but as practitioners in the field, it's basically pain that persists longer than you expect it to.

Q If we could turn to our next slide.

You have talked about some of these issues already in

15:32:05

terms of the patients you have seen, but here you're talking

specifically about some of the consequences of chronic pain; is that right?

A Yes.

Q And the word "devastating" is in here.

15:32:16 Can you explain why you used that word?

A Yes. Pain has a serious impact on patients. And again, I'm not talking about simple pain from a sprained ankle or pain after a wisdom tooth was removed.

We're talking about severe pain that persists that 15:32:32 affects people's lives in a terrible way. And if you're in chronic pain from a severe back injury, neck injury, nerve injury, multiple sclerosis, severe arthritis, brain injury, spinal cord injury, these are things that cause disability. And it is devastating. It affects every aspect of your 15:32:55 life. It affects your family relations. It affects your ability to work. It causes a tremendous amount of disability. It affects your mood. It causes a lot of depression and anxiety. So it certainly has huge economic effects.

15:33:11 This list is -- covers some of the things that you expect in chronic pain. Now there's a wide variation. Some are worse than others, but these are things I see every day.

You have impaired mental functioning when all you can concentrate on is the pain that you're having and it makes 15:33:29 it difficult to do other things.

Your quality of life is frequently not very good because you're limited in what you can do in terms of your activities. You can't get outside. You can't exercise as much as you want. You can't be with your family in the ways you're used to. You can't take your kids to school.

15:33:43

Impaired productivity. If you have significant chronic pain, you're not going to be able to work, be it from a nerve injury or just the pain itself can be devastating.

Unemployment is part of that, and I'm sorry to say that chronic pain is associated, especially poorly treated chronic pain, is associated with double the rate of suicide that we have in our population.

15:33:58

So that's just a measure of how severe chronic pain is.

15:34:15

Q As patients come to you with their chronic pain, is it your purpose to cure the pain?

A No. That's really not our usual goal, and, in fact, I -- it would be extremely rare to be able to cure someone's problem with chronic pain. Almost by definition, rarely are they curable. It's usually management. So -- because we're talking about situations -- and I just went through that long list. If you have multiple sclerosis, it doesn't go away. If you've had a spinal cord injury, it doesn't go away. If you have scar tissue on the nerves of your spine,

15:34:32

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it doesn't go away.

There's -- these are patients where surgery is not available to fix your particular problem. We refer to surgery for some patients and some problems can be improved with surgery, but they're the chronic pain patients. They're the ones who have a successful surgery. So it's a very challenging population.

Q Okay. I'd like to turn now to standard of care.

Are you familiar with that concept in the medical field?

A Yes, I am.

Q Can you explain it to all of us?

A Yeah. The standard of care would be what the predominant majority of physicians do in the regular course and practice of treating patients within their specialty.

Q How does a doctor know what the standard of care is?

A Well, doctors spend a lot of time in continuing medical education, and so we're constantly being updated, which is necessary and important because the standard of care changes over time.

Obviously, we learn new techniques, we learn new medicines as medicines become available through research. We follow research to see what's on the forefront, and so, yes, the standard of care does change and evolve over time. There's many different examples of that.

Q And how does a doctor or a healthcare professional know at any particular time what the standard of care is?

Is it written down somewhere?

A No. There's no federal guidelines that dictate standard of care. There's no regulation that dictates standard of care, and so basically it's a familiarity with what your colleagues and other people within your specialty and your level of expertise are doing on a regular basis. And frequently that's through meetings, it's through publications. Heaven knows we all read a number of journals as part of our life as a physician, and frequently continuing medical education, CME, is a big part of that as well.

Q CME is continuing medical education?

A Medical education, right.

Q I did not say legal, since that's what I'm used to.

We have heard previously about opioids within the standard of care for treating certain types of pain, including acute pain and cancer pain, cancer-related pain.

Are prescription opioids within the standard of care for treating chronic pain?

A Yes. Absolutely.

Q Before we go there, do you agree in terms of acute pain whether prescription opioids are appropriate treatments for acute pain?

A Yes, they are.

Q And what about cancer pain?

A Absolutely.

Q And tell us a little bit more about cancer pain and what that is and the affects over time.

15:37:41

A Cancer, everyone has a general idea of what cancer is, but it manifests itself in many different ways. The majority of cancer patients, though, have some pain, especially in a terminal illness with cancer. We're not talking about skin cancers or something like that, but in significant cancer that's life threatening and frequently takes life, there's a high percentage of patients that have pain as their primary problem.

15:37:58

Cancer tends to spread and go to the bones and other parts of the body, and that can be extremely painful. And so there's many different types of pain associated with cancer pain, but there's -- it's -- it can be devastating. And so there's a whole field of medicine oncology that oversees the treatment of cancer patients, and we work with oncologists a lot in my field to try to help patients with their severe pain.

15:38:13

15:38:34

Q Is there something known as end-of-life care when it comes to pain?

A Yes. End-of-life care can take many different forms, but hospice is a common type of end-of-life care, and those

15:38:47

are organizations that take care of patients with terminal illness. It may not be cancer. There's many types of things that may fall into the end-of-life care.

To be a hospice candidate, your life expectancy is expected to be one year or less, and that applies to people with end-stage heart disease, end-stage lung disease, many different conditions in addition to cancer, but it's usually caring for them for the last year of their life, and pain is usually a significant part of that treatment. So -- or situation that requires opioids and other medicines.

Q Shifting a little bit back, again, kind of over the scope of your career, the 37 years, has the medical community's focus on addressing untreated pain shifted over that time?

A Oh, absolutely. That was one of the, again, primary drivers for me getting involved in pain medicine. It was a new field. And in the '80s it was very clear that untreated pain was a huge terrible situation. And doctors were becoming more aware that so much suffering was out there and they needed treatment of some type. And part of that was procedural treatments that I was part of as well, part of that was opioids, part of it was other medicines, part of it is greater recognition using psychological techniques. So the field really has evolved since the '80s and '90s.

Q And what about specifically the use of opioids in

treating pain and chronic pain, has that been a part of the standard of care during the entire time you've been practicing?

A Yes. I had excellent training, like I think most other doctors in medical school. We knew that there's problems with opioids, but they were throughout my entire career, from the '80s on, part of the treatment. It's not the only treatment, of course. We've talk a lot about other things, but it was definitely part of the treatment for chronic pain.

Q You mentioned problems with opioids.

What do you mean?

A All medications have side effects and risks. Every single one. And opioids is no exception to that. And so there are side effects and risks. We have to counsel patients on this all the time. In fact, even for short duration of use of opioids usually you hear about the common things that can occur, everything from nausea and constipation, dizziness, sedation. Those are all easy, simple risks, and there are other risks that can also occur with longer use. You can have overdose. You can have opioid use disorder or addiction problems is possible as well. There's a number of different potential side effects with opioids.

Q Yesterday we had a witness who testified on a video

who is a former -- either former or current FDA official, I can't recall, and she talked about FDA approvals.

But I'd like to have you briefly talk about what your knowledge is of FDA approvals of opioids.

15:42:05 **A** Well, the FDA has approved opioids, and they go through the process. This is a list of opioids that most people might be familiar with some of those medical names, and we'll go through them a little bit later.

But the bottom line is the FDA goes through a process 15:42:23 of approval for opioids, or any other medicine. Every single medicine has to go through an approval process. And some of us are remotely familiar with that with vaccines now. That was for emergency use authorization. They don't do that for most medications, but it's a scientific panels 15:42:41 get together and study necessary research -- there's a lot of research that has to be done before you can get any medication approved, and the scientific panels look at the research, the outcomes and all the information. They look at safety and efficacy. And it takes quite a bit. You can 15:43:00 ask a number of companies how hard it is to get approval through the FDA for medications, but it's a tedious process. But that's in a nutshell what it is.

Q So as a prescriber of medications that are approved by the FDA, what is the FDA approval mean to you in your use of 15:43:18 those products?

A Well, number one, it's necessary for me to feel -- for me to prescribe something, it's going to have to be FDA approved for some indication, and it gives me a sense of confidence. It gives me a sense of confidence that it's been looked at for safety and efficacy.

15:43:34

Q Now, you understand that there are eight types of opioids that have been identified in this case at issue; is that right?

A Yes.

15:43:42

Q And on the screen we have those in front of you. And I don't need you to go through each of those, but do you agree that each of these, when used appropriately, are appropriate treatments for a doctor prescribing treatment for pain?

15:44:00

A Yes. Each one of these can be a part of a pain management program, yes.

Q Have you prescribed each of these opioids during your practice?

A Yes, I have.

15:44:10

Q One that stands out a bit because we've heard of a number of different times is fentanyl.

What is fentanyl and -- just what is fentanyl?

A Fentanyl is a -- what we call a synthetic opioid. That means it's manufactured. It's not derived from the opium plant. And it just so happens it's really, really

15:44:26

potent, and so my initial exposure was in anesthesia. We use it in the operating room, and it's very good to put people to sleep. It's also -- it is an opioid, so it's a very strong painkiller and has been used as an analgesic usually in patches, it comes in 3-day patch for use for outpatients, as well as some other formulations that are occasionally used for cancer patients.

Q For the FDA approved fentanyl, particularly the patches, why is that useful for cancer patients?

A Again, fentanyl is very potent. The other thing about fentanyl, just in terms of why it's useful, is while it's super potent and strong, it sometimes has fewer side effects of the itchiness and nausea and some of those minor side effects that can occur with opioids, so it is a useful alternative. Again, every patient is different and you have to individualize therapy, but fentanyl can be very helpful for cancer patients.

Q Now, you're also aware that there is fentanyl forms that are available as street drugs?

A Yes, I am.

Q Can you tell us the difference between the types of fentanyl that you may prescribe as a pain specialist and the street types of fentanyl?

A Well, there's a world of difference because one is medically regulated and you know the exact dose and exactly

what you're getting in the bottle or in the patch.

What you get on the street, you don't know anything about the dose or the purity or what it's mixed with, and it's been devastating. The illicit opioid epidemic has been devastating on -- and fentanyl, in particular, as we've all looked at the curves of increased opioid deaths, fentanyl has had a huge part of that in the last 10 years.

Q You mentioned dose. When you talk about fentanyl as a street drug, what's a dose?

15:46:34 **A** The dose is the strength. That's how strong. And you can think of it in milligrams. Fentanyl is measured in micrograms. It's 100 times stronger than morphine. So on a milligram-per-milligram basis, it's 100 times stronger.

Q And what's the significance of that?

15:46:53 **A** It's significant because it doesn't take very much to be off in your dosing. Since it's so potent and so -- you need so few micrograms to get an effect, if it's in a street drug, that's where you hear about so much of the problems, they mix it with heroin and cocaine and other things, and it

15:47:16 can be very fatal. Because these are not pharmacists making up these street drugs. These are done on the street by whoever is cutting the drug with certain other chemicals. And it's unregulated and just devastating to our public.

Q The jury has also heard in this case about

15:47:36 benzodiazapines, and on the screen in front of you we have a

number of them.

Can you tell us, just first, what is the purpose of a benzodiazapine in terms of appropriate prescribing?

A Right. Benzodiazapines, the most common, by example, would be Valium. Most people have heard of Valium. There's many others on this list. Valium is diazepam. Alprazolam is Xanax, that's a common one. Lorazepam is Ativan. Some of those you may have heard of. And the question was what are -- what is this class of medicine used for.

These are used for many different indications, but the big picture is they're used for anxiety. They relax you and mellow you in a way that can be very helpful for people with anxiety. They're also used for treatment of panic attacks. They're very commonly used in our veterans for PTSD, which is Post-Traumatic Stress Disorder, and that's a very common condition. It's used for many different indications by a host -- frankly psychiatrists use it the most. They specialize in mental health, of course, and they use a lot of benzodiazapines. We use it a lot at end of life with the anxiety and problems there. It's used in many different specialties.

Q And you say we use it, are you talking specifically about pain management specialists?

A No. I was kind of a global we as physicians use it in many different specialties.

Q What about in your practice? Have you prescribed the benzodiazapines that are shown on the chart in front of us?

A Yes, most of them. Not all of them, but most of those I have prescribed.

15:49:22 **Q** And I don't want you to repeat what you've already told us, but the times that you've prescribed it, can you give us examples why?

A Many examples. It's the diagnoses that I just went through. Sometimes I use it just short term. For example, 15:49:38 before an operation, before a procedure, we use a number of different medications to relax patients. It might be given in a shot or it might be a pill beforehand.

So if someone's coming in for a procedure, it's very kind to premedicate them to help with just the temporary 15:49:56 anxiety.

We also treat anxiety and PTSD usually in conjunction with other doctors, but also in our own format too.

We refer a lot to psychiatry to work together and co-manage many of our patients.

15:50:12 **Q** The jury's also heard a bit about muscle relaxants, and on the screen we have four of those.

Do you recognize these pharmaceutical products?

A Yes. Those are all four different muscle relaxants, yes.

15:50:25 **Q** What is the treatment, or what is one trying to treat

with these types of drugs?

A Specifically muscle spasm or spasticity, and that's a condition that can occur with any muscle injury or nerve injury. When you have an injury to the body, what the body normally does is it splints whatever, it can be an arm, it can be a leg, it can be a spine, it splints it, which means it causes severe muscle contraction so it doesn't move. It's the body's defense mechanism. To make a long story short, these medicines are specifically designed to try to relax tight, spasming muscles.

Q In terms of your use of these -- of medications with your patients, is it exclusively one or the other in terms of the classes, muscle relaxant or a benzo or an opioid?

A No. Like most things, all medical care is individualized. And, so, I certainly don't use all medicines in everybody. You have to -- everybody single case is different. And so you usually use a balance of medications. Again, it's always the least amount is best, we all know that. No one likes to take medicines if they don't have to.

But if someone has two different distinct problems that can be relieved with two different distinct drugs, yes, we use a combination of benzodiazapines and whatever other -- you know, opioid or opioid and muscle relaxant. To use all three together is uncommon. It is very uncommon.

But occasionally in certain conditions you may have to use all three. I can go through examples, but sometimes you use all of them.

Q If you could, give us example -- an example of a condition in which you might prescribe all three of these type of medications.

A One example would be spinal cord injury. So when you have a spinal cord injury, by definition it's going to cause pain. You're going to have pain in the lower body or below wherever you have the spinal cord injury. Furthermore, you're going to have muscle spasm and spasticity. It goes along when you have a nerve injury, the body's response, if the muscle is not getting the normal nerve signal that it's used to, it will react differently and spasm and not function correctly. It can cause spasticity where the muscles actually contract and get small, and that's very uncomfortable and painful when you have that muscle spasm. And frequently they're going to have some type of anxiety disorder as well, and so you're going to help them with the benzodiazapines.

Another example -- and again, I'll try not to take too much time with all this, but -- would be cancer patients. Clearly, cancer patients -- the percentage of cancer patients that receive both an opioid and a benzodiazapine at end of life is regular. One statistic I can throw out to

you that I'm familiar with because it was in my report was a study that looked at hospice patients at end of lie. And for their cancer patients, 99.8 percent of them all had opioids and 91 percent of them had benzodiazapines.

15:53:40 So in cancer, combination therapies are very common. So that's 9 out of 10 patients had both benzodiazapines and muscle -- and opioids. And I'm sure a few of those probably had muscle relaxants as well.

Q Switching back to the FDA for a moment.

15:53:59 Do you know what an FDA label is, or a label approved by the FDA?

A Yes, I do.

Q What is that?

A That's necessary documentation that must accompany a

15:54:10 prescription.

Q And if I can interrupt for just a second. When I think of label, I think of what's stuck on my medicine bottle. Maybe contrast it with that.

A So this is that small little piece of paper that comes

15:54:21 in the box. It's a small piece of paper with a -- well, I don't about small, it has tiny, tiny printing on it, and it has to come with each of the medicines that you're prescribed. Most people throw away, but it has very important information on it.

15:54:37 So this piece of paper -- and it may be more than one

page, it can be multiple pages -- has information that's required by the FDA as part of informed consent and disclosure. So when you get that medicine, ideally you look at that paper. And it has a lot of science in it, a lot of details, but it also uses some language, you know, that everyone can sort of understand. It's complicated sometimes, but it talks about the risks and side effects that require this disclosure with every prescription, even if it's just a blood pressure medicine or anything else.

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15:56:04

Q So as a doctor who prescribes these medications that have an FDA label, you may prescribe them multiple times, when a new product comes out, what is the significance of the label to a prescribing physician such as yourself?

A Well, we need to pay attention to it. We need to be aware of what's on it. It's very relevant because it's, in essence, FDA's communication to the patient, and physician for that matter, about the pros and cons, risks/benefits and side effects of that medication.

Q And do the FDA labels for opioids all warn about the risk of addiction and misuse?

A Yes, they do.

Q How long have they been doing that -- how long have the labels been doing that?

A As long as I've been in practice, at least.

Q Switching gears a bit, I think you've shared with the

jury your use or why you think opioids are appropriate treatments in managing pain.

How do you measure whether you're successful?

A That's a great question because that's changed over time. So if I'm dealing with pain, you're obviously going to have some metric or some measure of success based on how much better they feel, and that's really important, so that's part of it.

We also really measure in our field -- and this has been one of the things that's changed over the years -- with chronic pain, we don't expect perfection. We don't expect the pain to go away a hundred percent, so a probably better measurement is their level of activity. And that comes in a variety of different measurements.

So in some patients, just being able to get up in the morning and use the restroom by themselves is a success. If they could do that on a medicine and they could not do it when they are off the medicine, that's a success. For some patients it's being able to go to physical therapy. For some patients it's being able to cook their own meals. For some patients it might be able to do some minimal chores. But we measure the success in opioids now largely based on a combination of pain relief, some measure of pain relief, and increased function.

Q As you see patients over time, how do you actually

assess that?

A Yeah, we see patients frequently, on a regular basis. For chronic pain, it's necessary and helpful to be a really supportive role to see them on a regular basis. So our patients are seen on at least a monthly basis. Routinely, it would be unusual not to see that. So at monthly visits we try to accomplish many things, and monitoring their activity, physical activity, as well their emotional health and many other things is an important part of our function to monitor them.

Q Give us a little more detail. How do you do that?

What are you talking or testing patients on when they come back to determine their increased functioning?

A Well, it's mostly history, and it can be from the patient and their family and their activity level. And that's part of our plan. It's a part of our treatment plan. And we actually document that in the chart, and we have a level of expectation that the treatment that we're giving them is helping. And so we ask them verbally and actually look also physically at how they're moving, if they're walking better, if their physical exam has improved, and their report of physical activities at home is a good way to measure that.

Q One of the things you mentioned earlier was physical therapy. How does physical therapy tie in with pain

management?

A A great -- great question.

Because it turns out that in our field -- and it's true for really most medical problems, that the best outcomes usually come with increased activity and exercise. We all hear it from all of our doctors, you know, exercise, exercise, exercise, but it's really true, especially in chronic pain. And when you have any disability, the more active you can be, the more you can move the muscles, the more you can move the joints, get range of motion, get more activity, the better they're going to be.

And so that's part of our plan, is to make circumstances, design a treatment program where they can have increased activity, and just the increased activity -- and physical therapy is a key part of that because they help you with increasing activity. They'll move your leg for you to get you warmed up. They'll work on your range of motion. They'll train you how to exercise. So it's very important in chronic pain to include physical therapy and any exercise that's possible. Not everyone's able to exercise well, but even in bed you can do exercises. So we emphasize that a lot because that's -- that can make a big difference in the quality of life.

Q So as you look at patients and who they encounter during their treatment of their pain, a doctor such as

yourself, perhaps a nurse in your office, a receptionist in your office, the pharmacist who may fill a prescription, who's best situated to make those assessments that you just talked about?

16:00:37 **A** Well, those are kind of medical decision-making issues and so as a physician, I need to quarterback those types of activities, and I have access to all the information in terms of, you know, who I referred them to, what medications they are using and why I'm using them and what their history

16:00:55 is in the past and response to a variety of different medicines. And so you're kind of talking about medical decision-making with as much information that we have available to us is critical and that's -- the physician is in the best place to do that.

16:01:11 **Q** What about your experience over time, does that matter?

A I think so. I think experience helps.

Q And similar question with respect to assessing the foreseeable risks that you talked about with opioids versus

16:01:24 the benefits a patient might achieve.

Who's in the best position to make that assessment?

A Well, again, you're referring to medical decision-making in terms of knowing the pros and cons and risks of prescribing any medication, and especially opioids.

16:01:39 It's very important to have all the information

available because genetics plays an important part of it, so you need to know their family history, you have to know their personal history of what they've done in the past, what they've been exposed to, how they've responded to medications and so forth. So you're talking about all the information that goes into the medical decision making for the physician.

Q In your experience, are you familiar with the risks of addiction and opioid use disorder?

A Yes.

Q Okay. Tell us just a bit about -- because we've heard quite a bit already. From your standpoint, what is the concerns that you have in prescribing opioids -- the concerns you may have in prescribing opioids with either addiction or opioid use disorder?

A We are all aware, all physicians are aware that opioids can be addictive. They can cause problems with misuse, which is what we use typically as a term for less severe problems where they may just run out of their medicines early on a regular basis or other things, but there's a risk of misuse and addiction.

Now, addiction is a severe problem. It's a psychobehavioral problem which is a severe problem that needs significant attention. So we are very careful in, number one, screening our patients before they're started on

opioids to make sure that they're good candidates, and then most importantly, you monitor them on a regular basis. And there's many tools that we use to monitor them for that.

One is the regular visits, that we see them on a regular basis. Urine drug testing is really important to make sure that, number one, the drug is there and that there's not other illicit drugs present in there.

We do a lot of different monitoring, everything from pill counts to talking to other family members, seeing how the patient's physical examination is, many different things that we do to monitor how a patient is responding so you can avoid getting opioid addiction.

Also, expectation management and counseling is really an important part of that.

Q How do you monitor your patients for possible physiologic dependence?

A Well, physiologic dependence is not specifically related to addiction.

Q Maybe I should start with, why don't you tell us what physiologic dependence is?

A Yeah, that's a characteristic of many different medications, and it's just a medical term. If you're dependent on a medication, it means that if you have an abrupt stop of that medicine, if it's stopped abruptly, you will go through physical problems. So that happens in many

different medications.

It happens with insulin. If you stop insulin, you have terrible -- you could die.

If you stopped steroids that you're on for different medical educations [sic], you can actually have a fatal reaction.

If you stop opioids, you can go through withdraw, and withdrawals are -- a very bad thing. It can be devastating, and in some cases fatal.

So dependence is just a term saying that if you stop something, there will be physical manifestations. It's not the same as addiction. You can have someone who has no addictive qualities at all with an opioid or another medicine, and if you stop it abruptly, inappropriately, I would add, because you never want to stop an opioid abruptly because predictably, if they're on enough of it to cause dependency, you're going to have withdrawal symptoms.

Q How do you know if your patient is becoming addicted to opioid treatment?

A Well, the definition of addiction has a number of different things that you look for. There's actually, by the DSM-5, it's a -- the psychiatric definition that's widely accepted, there's 11 different determining factors.

And so you look at each one of these as, if they're positive or not, as going toward the syndrome of addiction

or opiate use disorder. Those are both used pretty interchangeably.

So addiction has these different qualities, and I think you've probably already talked about them, but I -- just from -- in a nutshell, addiction is most well represented by cravings, compulsive behavior, and lack of control, and doing self-harm socially, family, economically and so forth. So addiction is allowing self-harm in that setting and being out of control.

16:06:46 **Q** Given the consequences that you just described, how important is it to you in treating your patients to watch or addiction in your patients?

A It's severely important. It's part of our routine office visits all the time. Every time we see a patient who's maintained on opioids we address issues that pertain to any of the risk factors for addiction are something that's really important. We take opiate prescribing very seriously, and I think that's common for most doctors. It would -- we're all aware of the significant risks. And so that's why we monitor our patients. And I think we really improved their dramatic --

MR. LANIER: Your Honor, I'll object to him testifying for all doctors.

THE COURT: Well. . . all right.

16:07:37 If you could, Doctor, speak for what you do in your

practice, or you can refer to the standard of care.

BY MR. MAJORAS:

Q This goes back to what I asked you at the outset, as you offer opinions, I'd like to make sure you offer it within a reasonable degree of certainty within your specialty and standard of care.

16:07:52

So let me ask you first, the things that you're talking about, do those fit within the standard of care for your specialty?

16:08:01

A Yes.

Q Okay. And if there's more to your answer, please continue.

A So one of the -- we were talking about monitoring and avoiding addiction. And part of the monitoring process --

16:08:17

again, there's multiple different steps and considerations, but if you pay close attention to a patient, you will pick up any potential problems early. I'm not saying doctors are perfect at diagnosing addiction, they're not. It's a very difficult syndrome, and there's a lot of variation.

16:08:34

But the bottom line is with good attention to detail and monitoring your patients with a lot of the things that I've said, from urinary drug testing and frequent visits, pill counts, you can do other things in terms of following the PDMP to make sure they're not doctor shopping and so forth, watching their behaviors carefully, the incidence of

16:08:55

addiction in our practice is rare.

Q When you say rare, do you have any specific number you can put on it?

A I can't put a specific number, but in our practice it would be less than 5 percent.

Q I'd like to compare a bit to the types of patients you're talking about and that you're seeing and the monitoring that you feel like you need to do versus a prescription for opioids for short-term duration, such as dental care or things of that nature.

Are they the same for both?

A You're asking by the risks involved for addiction?

Q Yes, sir. The risks and the need for monitoring.

A No. So if you've just gotten the short-term thing from the emergency room or your dentist or something like that, you're not going to be experiencing any of these other more advanced techniques. It's a short term.

While there is some debate about having addictive possibilities with short term, it's extremely uncommon and the risks of addiction increase with the higher -- or longer duration of use of opioids as well as higher doses. You can have increased risks over time.

Q So we talked about the benefits you've seen from opioids, and we just talked about certainly some of the risks.

Are there consequences in treating pain and managing pain with focusing only online abuse issues?

A Well, the DEA has made comments about that that I put in my report, and the fact is you should not -- yeah, focusing only on the abuse potential of a drug could erroneously lead to the conclusion they should be avoided. And so clearly the vast majority of my patients don't suffer from opiate use disorder or addiction, and so I find the medication, and many other doctors do as well, very useful in chronic pain. And that's being aware of the fact that there are risks.

Q In looking at the quote that you put up, this is from materials in your report that you cite; is that right?

A That's correct.

Q And who issued this statement?

A The DEA in combination with 21 other organizations.

Q It was part of a longer report; correct?

A Correct. It's a consensus statement, yes.

Q Just going to the end of it, the part you didn't read, and I'll just do the whole thing. Focusing only on the abuse potential of a drug could erroneously lead to the conclusion that these drugs should be avoided when medically indicated -- which you just talked about -- generating a sense of fear rather than a legitimate respect for their properties.

What's the fear?

A Well, there's been so much press and publicity about opioid addiction that many of our patients, and physicians for that matter, are very fearful for using opioids. And if they don't have significant experience and training regarding that, that can be fearful. And I think that's very common.

Q When you have patients -- well, let me ask first. Have you had patients who have expressed that type of fear?

A Yes, I have.

Q And what is your advice that you give to patients when you're discussing that issue?

A I always give them a choice. It's always up to the patient whether they want to try opioid therapy, and it's based on a conversation of -- with informed consent about the risks and benefits. And it's not right for everybody. And a lot of my patients -- not a lot, but a certain percentage of patients will refuse an opioid, and that's okay. That's, again, totally up to the patient to decide. But I give them the risks and benefits to let them make the decision.

Q So it a patient refuses your recommended treatment of an opioid, is that give-up time? What do you do?

A No. No. We never give up on patients, but we would have to consider other alternatives. I mean, there's always

other alternatives. Some of that can be supportive therapy. It can be a revisit to other treatments we've tried in the past and maybe things have changed. It can be using other medicines to help as best we can. But we don't give up on patients actually. We try our best not to abandon our patients.

Q We've spoken quite a bit about chronic pain. I'd like to turn to acute pain.

In your practice over the 37 years you've been doing this, do you treat both types?

A Yes, I do.

Q Sir, what is acute pain?

A Well, acute pain is that short -- a pain that it's expected to last a short duration.

Q And how are prescription opioids viewed within the standard of care in treating acute pain today?

A Well, there's no question that for acute pain, and -- I could go through the long list, we've talked about it a little bit already -- there's no question that opioids can be very useful in acute pain.

Q And when did that first become part of this, looking back over your time and as a pain specialist, when did opioids first become within that standard of care?

A It's always been part of the standard of care during my career, and to my knowledge, way before then for the

treatment of acute pain.

Q So opioids carry the same value for all patients?

A Yes.

Q And by value, I'm not talking about a monetary value, I'm talking a value in treating the pain.

A That varies among patients and their medical condition. So opioids are not right for everybody.

Q What do you mean?

A Some patients have problems with side effects of opioids and just don't tolerate them. They can have terrible nausea and vomiting. They may get sedated or have dizziness or have other side effects. Constipation can be intolerable, and they may not be appropriate for everybody.

Q Do opioids have any medical benefits in treating non-pain conditions?

A Yes. There's at least two non-pain conditions where the treatment of choice are opioids. One is sleep hunger, and -- I'm sorry. . . I'm sorry, I'm flashing on the name, but air hunger is what I was looking for, and that's a condition that's most common at the end of life where people are gasping for breath, and that specific syndrome can be associated with a number of different conditions. It can be end-stage respiratory problems, it can also be related to even anxiety associated with end of life, and the treatment of choice for that are opioids. And again, that's not pain.

There's no pain involved at all, but opioids are the treatment of choice for air hunger. It can be a devastating picture if you have a family member suffering from that.

The other condition of which opioids are the treatment of choice is addiction. Addiction's best outcome is what we call medication assisted therapy, and the treatment -- the medical treatment for addiction currently is the use of opioids long-term.

16:16:23

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Q We talked a bit about opioids and the benzodiazapines, and you talked about how there are times when they can be prescribed together appropriately; is that right?

A Yes.

Q How commonly are opioids or benzodiazapines prescribed to patients at the end of life?

A Frequently. I threw out those numbers before and this slide, for example, shows the recommended medications --

Q If I could just interrupt you for a second.

A Sure.

Q Let's be sure everyone understands what we're seeing here on this slide. Could you explain it a bit?

A Yeah. This slide was a list of medications requested by the World Health Organization and developed by the International Association For Hospice and Palliative Care.

So this is a list of medicines that are commonly used for hospice, and again, we talked about hospice as being

end-of-life care. And on that list there are a number of opioids and benzodiazapines, which are so commonly used together. I mentioned those statistics earlier.

Just in all hospice patients, I mentioned cancer, if you have cancer in hospice that it was 98 percent opioids and 91 percent benzos -- for -- if you take all patients for end of life, even outside of cancer, in this same study on hospice patients, 84 percent were receiving opioids and 84 percent were receiving benzodiazapines. So, again, another example where co-prescribing of those two medications is common.

Q If a patient doesn't have the ability to have opioids prescribed in these end-of-life situations, or benzos, what is the result?

A Unnecessary suffering. It would be -- it would be terrible.

Q Are they only prescribed in end-of-life treatment?

A No. No. These same medications that we're talking about are the same ones that we use -- many physicians use on a regular basis and in our practice we use on a regular basis alone or in combination.

Q If we could turn to the next slide, just following up your comment about many practices, are these some of the specialties that prescribe opioids?

A Yeah. This is not a complete list, of course, but

these are just some of the specialties that routinely prescribe the opioids on a regular basis as well as addiction medicine would be on that list as well and any other procedural specialty and many others.

16:19:19 **Q** And we've talked about already the primary care providers, hospice providers, pain management doctors, and oncologists, doctors who treat cancer.

Give me just a brief outline of these other specialties and why they are prescribing opioids for pain

16:19:39 treatment.

So start with emergency medicine.

A Sure. Well, emergency medicine by definition, they're seeing urgent cases, and one of the most frequently described problems arrive in the emergency room are painful. It's pain. But it may be pain related to a broken injury, a

16:19:53 sprained ankle, a terrible back. Pain is probably the most common presenting symptom in emergency rooms. So they use opioids routinely all day long.

Q How about urgent care? It sounds like that may be the

16:20:14 same category.

A Urgent care, express care, yes, same thing.

Q You've talked about surgical specialties I believe already. One you haven't talked about is OB/GYN's.

How are opioids used in those practices?

16:20:27 **A** Well, women will always know better than men how

painful delivering a baby is.

Q And you may have mentioned some of this already, I apologize, but please go ahead.

A And so pain after a delivery, and, of course, any gynecological procedures are frequently painful, so any physician that does procedures on patients, typically there's going to be pain after that procedure. If they have to cut the skin or whatever they're doing, and opioids are used routinely for pain after procedures.

16:21:02 **Q** And I think we've picked up on some of the others. The last one I'll ask you about on this list or podiatrists.

A Right. Those are foot doctors, if you will, and they're trained to do treatment, including surgery of the feet, and they treat everything from bunions to hammer toe and a lot of other things, and so they also do procedures that are painful and require the use of opioids.

Q And if you were to break down this list, I'm going to ask you whether you can break down this list between the types of practices that are generally prescribing for acute pain versus chronic or possibly both, how would you do that?

A Well, clearly, most are acute pain, kind of short-term treatment, but certainly oncologists and pain management doctors and hospice providers, those three would be classically treating both acute and chronic.

16:21:59 **Q** So I'd like to turn back now to standard of care

generally within your profession and the treatment of pain.

Have you seen that evolve over time, especially with respect to using opioids?

A Yes, it's changed significantly over the decades of my practice.

Q We've heard some testimony earlier in this case about a paradigm shift in that regard. Would you agree with that statement -- with that -- I'm sorry. Would you agree with that characterization?

A I would. There's been a significant change in attitude regarding the treatment of -- treatment of pain, especially chronic pain, over the last few decades.

Q And with respect specifically to opioids, has there been a paradigm shift?

A Yes. Yes. Very true.

Q We're going to talk about that in some detail. But could you give us an example of simply what you mean by standard of care changing or evolving over time?

A Well, again, that's reflective of the practice of the majority of physicians regarding certain conditions. And the bottom line is we became more aware in the '80s and '90s about the amount of untreated pain.

And so there became a lot of work and a lot of actually organizations that helped with continuing medical education and awareness, everything from the Joint

Commission For Accreditation to the Veterans Administration, and even the DEA was making physicians more aware of treatment options and the undertreatment of pain.

So that was an evolution that occurred over many, many years. And this started at least as -- when I was in training.

Q And, Doctor, I'm sorry, I didn't mean to interrupt, but Dr. Wailes, as you talk about that shift in pain treatment, how does that compare to just generally how standards of care shift within the medical profession?

A Well, certainly they occur frequently. There's many different examples of changing the standard of care. Everything from the position of a baby in a crib all the way to the use of insulin.

Here's an example. Baby in a crib. When my children were born, all babies were face down in a crib so you would avoid sudden infant death syndrome, and they were religious about it. Both my wife and I complied with that just religiously for our three children, and then about 10 years later, all that standard of care for children changed completely, and any one of you know -- around any babies now, they only let them go to sleep on their back. That's just one example.

There's many other examples about the change in care over time for standards of practice. Everything from

treating diabetics with insulin has changed over time. Aggressive treatment of heart conditions have treated -- changed over time. The evolution of medicine hopefully and luckily does improve over time.

16:25:05 **Q** So shifting back to what you were talking about before I interrupted, and again, I apologize for that, you were talking about the changing standard of care and using -- treating pain with opioids.

Are you familiar with the phrase pain is the fifth

16:25:22 vital sign?

A Yes, I am.

Q Before we talk about the fifth one, what are the first four?

A Well, the first four are regular -- what we call

16:25:30 regular vital signs: It's blood pressure, pulse, temperature and heart rate -- or respiratory rate.

Q And you said you're familiar with pain as the fifth vital sign. What is that in reference to?

A Well, that was a new concept that came about in the --

16:25:45 I believe it was the '90s, and it was a recognition that that was something else that's vital to how a patient's doing and should be measured. So that's why it was called a vital sign.

Vital signs are those numbers that I just said, the

16:26:00 four standard things of blood pressure and so forth, are

things that are routinely measured at your doctor's office and certainly routinely measured by nurses in a hospital. They check your vital signs on a regular basis. And pain was never routinely measured, and so there was a move at that time to make pain measurement more common. And by making pain the fifth vital sign, it made it part of institutionally hospitals and other healthcare providers so it would get the more important and necessary recognition.

Q Let's take a look at some of those publications that came out. The first is I'd like to refer you to exhibit WAG-MDL-2457.

If you can bring that up so. . .

Do you recognize this document that is on the screen in front of you?

A Yes, I do.

Q I'm sorry. We'll wait till everybody has a chance to have a copy.

So first question is, do you recognize this -- the first page of this document in front of you?

A Yes -- yes, I do.

Q Okay. What is it?

A It's a document produced by the Department of Veteran Affairs that's reflecting -- it's a toolkit to help people utilize pain as the fifth vital sign.

Q This is dated October 2000?

A Correct.

Q Do you recall when this came out?

A In general terms. I don't remember the exact date, but it was -- yes, in general terms, yes.

16:27:51 **Q** Why do you remember it? Why do you remember generally the fifth vital sign material coming out into publications?

A Well, it was part of that trend toward greater recognition of the undertreatment of pain. There's a huge trend, and this was part of it, and again, this kind of made 16:28:07 it more common for people to pay attention and brought it to the attention of many, many other physicians and as well as patients.

Q A little bit earlier in your answers you talked about the joint commission.

16:28:22 Do you recall that?

A Yes, I do.

Q What is the joint commission?

A The joint commission basically accredits hospitals and other healthcare institutions, and they're tasked with 16:28:38 making sure that there's quality, and that involves everything from sterile operating rooms and appropriate nursing conditions for them to be certified and to be able to take care of inpatients.

Q And did the joint commission lend support to the idea 16:28:55 that pain is the fifth vital sign?

A Yes, they did.

Q I'm going to ask you to take a look at another document. This is exhibit WAG-MDL-1005. We'll wait till it gets passed out.

16:29:11 It's already been passed out.

And, Dr. Wailes, you may have -- you have that on the screen in front of you. You may also have the paper copy if you prefer it, if you want. Screen works?

A I see it, yes.

16:29:22 **Q** Okay. Could you tell us what this is on the screen in front of you right now?

A Yeah. This is an explanation of the joint commission and what they're looking at in terms of utilizing the measurement of pain.

16:29:40 **Q** And the date of this is December 18, 2001?

A Correct.

Q Do you recall when this document was released by the joint commission?

A Only in general terms. I don't remember the specific

16:29:51 date, but I remember in general terms it coming out.

Q If we could go to Page 12, which scares me because it says 1 of 10 at the top.

But magically here we are. And in particular, can you tell us what the joint commission in this document is saying

16:30:16 in terms of pain being the fifth vital sign?

I believe it comes under -- right in the middle of the document.

A Yeah. It actually is in two sections there. The top section -- actually, it says, pain can be a common part of the patient experience.

Q Just if I could stop you just a moment. We'll blow this up a little bit so everyone can see it.

Okay. Go ahead. If you want to read that, go ahead.

A Yeah. Thank you.

And unrelieved pain has adverse physical and psychological effects, and they're making the very clear point that the patient's right to pain management is respected and supported.

And then the next section goes into --

Q Let's stop just a bit. We'll blow it up. And I'll ask you as we're reading, since we all tend to get fast when we read, if you can just do it slowly, please.

A I apologize for that.

In this section they talk about the fifth vital sign, using the measurement of pain as the fifth vital sign.

Q And you talk about the evolving standard the care.

How does pain being the fifth vital sign of the types of documents we're seeing impact the standard of care during this time period?

A So with greater recognition and people paying

attention to pain, there certainly is going to be more treatment of that pain. So when you assess somebody and they're uncomfortable, you want to give them choices of how they can improve their pain and give them options for treatment. And so that's -- that's part of the evolution, this -- again, understanding the undertreatment of pain, a lot more attention toward what was going on in patients' lives, in the hospital, other places, drew more attention and in response to that, they received more treatment.

16:31:37

16:31:58

Q Let's look at a few more -- or at least one more example of this.

In particular I'd ask that exhibit WAG-MDL-1355 be pulled up.

This is a document you cite in your report as something you've relied upon; is that right?

16:32:20

A Yes.

Q What is the significance of this document, and perhaps the part that we now see blown up -- well, go ahead, please leave that there.

16:32:32

Mr. Ferry, would you please blow up that portion of the document? Thank you.

What effect does this document have as you reviewed it for your report?

A Yes. This is a document that we did refer to earlier, which is the DEA in conjunction with 21 other organizations

16:32:47

doing a consensus statement, and this shows the section, the first part is it recognizes that drug abuse is a serious problem, and then it goes on to say what we quoted earlier, is that focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated.

And, anyway, it was a statement that was, in essence, endorsing the appropriate treatment, and that can include opioids, for pain.

16:33:32 **Q** So as you look at the evolving standard of care for treating pain, particularly as to opioids, what have you observed in your practice and the work you've done in these medical associations about the use of opioids over time by prescribers?

16:33:50 **A** Well, I would recognize what we've all been exposed to probably in graphs. I've seen the graphs of the increased use of opioids over time and it's a -- it's a significant increase over time from, in essence, the '80s all the way to 2011, and then after 2011, prescription opioids have fallen 16:34:12 43 percent until 2019.

And I haven't seen as much data since then, but that's been the course, specifically the evolution of increased use of opioids over many years, and then the last 9 years, or 10 years, the number of prescriptions have fallen off.

16:34:32 **Q** And in your opinion, the increase that you saw and

then the decrease --

A Correct.

Q -- that you saw in prescribing, was that consistent with the standard of care in the treatment of pain over the time period you've talked about?

A Yes, it was, and it reflects many different considerations. The standard of care in the '80s, '90s, and 2000's included the use of opioids. We're talking specifically about opioids now, but other pain treatments were also going concurrently. But the use of opioids during those times increased dramatically, and that had to do with greater recognition, it had to do with greater awareness and knowing there was an undertreatment of opioids. It also came along with a different concept of how to prescribe opioids.

For most physicians, using opioids was not very familiar because historically in the -- in days and months -- or I'm sorry, in decades previously, opioids were not used as often. And so I think that there was also a learning period during that time where physicians became more aware of opioids and their usefulness, and we also became more aware of the risks of misuse and the risk of addiction. And -- and because of those -- that awareness, the standard of care changed, and with that increased awareness and education, there became fewer opioid

prescriptions. And again, it's fallen off 43 percent in the last 9 or 10 years.

Q Do you recognize the name Joe Rannazzisi, a former DEA official?

16:36:21 **A** Yes, I do.

Q In fact, you cite some testimony of his in your report; is that correct?

A Yes.

Q And I'll tell you, at trial a couple weeks earlier

16:36:29 when he testified, he acknowledged that when he testified before Congress in 2012, he said that 99 percent of doctors were perfect.

What's your reaction to that?

A My reaction is thank you, and I think that's a

16:36:45 recognition that most doctors are really legitimate and appropriate and well-trained and are doing the right thing.

Q And have you run across doctors that you believe fall within that 1 percent?

A It's extremely rare, but yes, I have.

16:37:01 **Q** And has that been as part of your work with the California Medical Association?

A California Medical Board.

Q I'm sorry, California Medical Board.

A Yeah.

16:37:09 **Q** That's the one in which you review cases brought

against prescribers from time to time; right?

A That's correct.

Q You mentioned earlier in your testimony using a PDMP. And you're licensed in California; right?

16:37:34 **A** That's correct.

Q I think you acknowledged that you knew the Ohio PDMP is known at OARRS?

A Correct.

Q What's the California system?

16:37:41 **A** It's CURES.

Q CURES. C-U-R-E-S?

A Yep. That's it.

Q It's easier to remember than OARRS.

Tell us the significance in your practice as treating

16:37:55 pain of using PDPM systems, like CURES in California?

A Well, PDMP, this OARRS in Ohio, has been required for our use. It's been available -- in Ohio I think it first came out in 2006 and has been required for use by statute in 2015 for all physicians, and pharmacists use it as well.

16:38:20 And what it is is the database that looks at all the other prescriptions for controlled substances, including opioids.

So how you -- I use it in my practice is we use it routinely. On every single patient basically every single visit, we pull that report up. And what it allows us to do

16:38:40 is to see if they're getting some other sources of opioids

from other physicians. They may have had a trip to the emergency room or something else, and we'll ask about that. And so we do pay attention to that. And I think that's important. It's not the -- you can't just use that one measure.

In fact, in my report I cite a number of studies that show that just that one measure alone isn't very good for screening for doctor shopping, but it's one of the things we use to look at the history of the patient and keep up with their other prescriptions.

Q You've spoken about the interactions -- I'm going to switch gears here. You've spoken about the interactions you have had with pharmacists during your career treating patients. I want to do -- I want to take a closer look at that.

Who has the responsibility for treating a patient, according to medical judgment?

A That would be physicians.

Q And if we look at slide 21.

It's okay. While we're searching for slide 21, it's pretty easy. I can read this. Would you agree with the following statement: It is up to each -- it's now on the screen.

It is up to each DEA registered practitioner to treat a patient according to his or her professional medical

judgment as long as it is generally recognized and accepted in the United States?

Do you see that?

A Yes, I do.

16:40:13 **Q** Now, do you know what that's from?

A I believe that's from the DEA.

Q And when the phrase is generally recognized and accepted, is that the same that you've been talking about in terms of what the standard of care is for a physician?

16:40:26 **A** In essence, yes.

Q And if a doctor is prescribing opioids consistent with that standard of care, do you consider that to be legitimate medicine?

A Absolutely. It would be a legitimate prescription, 16:40:42 legitimate practice of medicine, yes, it's within the standard of care.

Q Based on your review and in your experience from the perspective of a doctor, what are the pharmacists' responsibilities as they relate to prescriber and patient?

16:41:00 Slide 23, please.

A Yeah. The pharmacist has a very important function, and this slide outlines some of them, not all, but it is really important for screening the prescription for overt errors. It could just literally just be a decimal point or 16:41:19 something wrong if it's digital or bad handwriting,

potential allergies, adverse medical interactions, forgery, fraud, and diversion. Those are important functions of the pharmacist.

And another one I would just throw in there as well, I think it's important, is counseling.

Q What do you mean by counseling?

A Giving the patient the opportunity to get more information about the drugs they're receiving, because they're willing to do that for any prescription they provide typically. They're willing to do it. They don't routinely do it necessarily, but -- and again, I'm not a pharmacist, so. . .

Q You already told us that you as a doctor talk to them about the risks and benefits of the products.

A It is critically important that doctors cover that. That's a necessary and vital function of physicians to cover those items, yes. Informed consent.

Q And do you have a -- an expert opinion based on your review and experience as to whether it is appropriate for pharmacies or pharmacists to make decisions about whether a patient's disease or condition deserves or warrants a prescription prescribed by a doctor?

A I have strong feelings about that, that that's medical decision-making and very important that the physician who has all the information, they have the history, the

physical, the background, the labs, the experience, and all the information that it takes to make a medical decision should be solely with the physician.

Q Do you believe it is ever appropriate for a pharmacist to refuse to fill an opioid prescription that is written by a doctor?

16:42:55

A Yes. I think the doctor -- the pharmacist always has the right to refuse a prescription. That's -- I think pretty much everyone agrees with that. They have to be the final judge, and it's based on all the factors that they have exposure to. So there are examples where the pharmacist would have responsibile action refusing a prescription.

16:43:12

Q You mentioned that you have had pretty regular contact with pharmacists in relation to your prescribing of opioids; is that right?

16:43:31

A Intermittently, yes.

Q In terms of --

THE COURT: Mr. Majoras, there's some slides on here, and I'm not sure where they're coming from.

16:43:42

MR. MAJORAS: Let's take those down, please.

THE COURT: Thank you.

BY MR. MAJORAS:

Q Okay. You said intermittently. And I think it was time for my question, so I'll ask the question.

16:43:54

In terms of your discussions with pharmacists, have they raised with you the appropriateness, in their view, of prescriptions you've written?

A That would be very uncommon. It was more common many years ago for a brief period of time, but currently, that's not a regular occurrence at all.

Q Are you well known in the San Diego area as a pain specialist?

A I believe so.

Q Are there risks in delaying or denying an opioid prescription that has been appropriately written to treat a medical condition?

A Absolutely.

Q What are they?

A Yeah. That's -- even the delay of a prescription that can cause withdrawal symptoms can be devastating. So to deny or delay a prescription for an opioid where a patient needs them on a regular basis can initiate withdrawal and can be devastating and even life threatening. So that is a serious problem.

Q And are there consequences to abruptly reducing or stopping a patient's opioid medication just generally?

A Yeah. If they're on a certain amount of opioid where they're going to have withdrawal symptoms by stopping it abruptly, then yes, that's a serious problem of delaying or

denying and they -- again, it can be devastating. It can cause severe patient harm and even death if an opioid is acutely, suddenly withdrawn or even delayed.

Q Let's take a look at a couple of additional materials that you cite in your report. The first is Exhibit DEF-MDL-11040. If we just wait a moment while that's handed out.

They've already got it. Thank you.

So if we could put the -- that exhibit up, the first page of that exhibit.

We have technical issues on that exhibit. Let's go to a different one. Thank you. Thank you, Mr. Carter. Let's do a different exhibit.

Let's look at Exhibit DEF-MDL-11963. If we could pull that up to Page 1.

First, before we get into any of the specifics, could you tell us what this document is and why you cited it in your report?

A Yeah. This is a reprint of an article that -- where the CDC came out and tried to correct some misapplication to their guidelines which came out in 2016.

Q And if we look to -- the CDC is the Center for Disease Control, I think?

A That's correct.

Q All of us now know what that means over the last two

years; is that correct?

A Thank you. Yes, it is.

Q And if we look to I believe the third bullet point.

If we can blow that up, please.

16:47:31 And how does this bullet point relate to what you were just testifying about?

A It basically reiterates exactly what I was saying, that no one suggests the abrupt tapering or sudden discontinuation of opioids. The risks of abrupt changes can

16:47:51 be devastating and very harmful to patients.

Q I said to a witness earlier, when I'm flipping pages, that's always a good sign.

And the opinions that you've been offering about the standard of care, is it your opinion that that's the

16:48:25 standard of care throughout the United States?

A Yes.

Q And would your opinions about how a pharmacist should handle prescriptions written by a prescriber like yourself differ from state to state?

16:48:41 **A** I don't believe so.

Q Okay. I'm going to now switch to another part of your opinions in this case, and this relates specifically to red flags.

I believe I mentioned earlier that in your report and

16:48:55 the opinions you've offered in this case, you've taken a

look at the opinions put forth by Mr. Catizone about red flags; is that right?

A That's correct.

Q So I would like to ask you as a pain management doctor who regularly prescribes opioids, your opinions on some of the elements or characteristics of Mr. Catizone's red flags; okay?

A Okay.

Q And I think you said you reviewed all of his red flags at the time you wrote your report?

A Yes, I did.

Q And I will just remind you that his testimony in this case was consistent with what was in his report about the red flags. Okay?

A Okay.

Q Before we get into any individual red flags, can you tell us generally what your view is of how the red flags as described by Mr. Catizone would impact the practice of pain management?

A To answer that question I first have to distinguish how his red flags -- Catizone's red flags are very different than what a normal red flag is.

A red flag is just a concept. We're all kind of familiar with what a red flag might be. It's something that draws your attention to an issue. So there could be red

flags in any industry, but -- so a red flag is something that draws your attention and needs -- needs to be addressed in some way to make you more comfortable. We see that in all of our prescribing, as we prescribe. If there's something we're worried about, that would be in general terms a red flag.

But this is in sharp distinction from Catizone's red flags. Luckily they're not anything like that in practice today, but what he's proposing is a situation where all of his red flags -- and we'll go through some of those -- have to be applied and have to be resolved or the prescription should not be dispensed. That's huge.

What that means is that it's not just a prompt or something to get your attention, it means this is a mechanical way or an algorithm -- like an algorithm of how to dispense medications. And if in your algorithm, in this system, you can't check the box, that you've cleared up this red flag, then you cannot dispense. He's very absolute and strong about it in his report about not dispensing that. And that is a significant problem that we need to address. And I'm happy to talk more about that now.

Q So, first, though, before we go to that, are you saying that there should never be any concerns that a pharmacist can raise about a prescription that he or she sees in front of her?

A No, I'm not saying that at all. Again, I believe red flags are legitimate, and pharmacists are trained, I'm told, to look for different red flags. And there are a variety of things that you would see that might prompt you to do more research or have concerns or, again, be aware of and address in some way. And we'll go through lots of examples of that.

So I believe in red flags. Red flags, the concept is important. Is it means they're using their judgment and caution. And I believe in pharmacists using their judgment, and luckily they do now. But what Catizone's red flags are suggesting is that if for some reason they can't resolve it -- and we can talk about how they don't resolve it -- if they call the doctor's office and the doctor's closed and they can't get a hold of an on-call doctor, if the doctor tries to call back to the pharmacist and the pharmacy is closed, there's many different circumstances where they may not get a hundred percent resolution of his Catizone red flags, and if that's true, he's saying don't dispense the medicine.

And we'll go through the examples of his red flags and I'll be able to show you that so many of them are commonplace, normal situations, but he's flagging them and saying do not dispense unless it's completely resolved.

Q What is the consequence to you as a doctor treating pain if legitimate prescriptions get caught up in the

mechanical process that you just described?

A What it means is that my patients can be harmed. If my patients are on opioids and they're delayed or denied, and just delayed is enough, they're going to go through withdrawals. And that is devastating. Patients under my care I would never, ever want it that to happen. That -- that's significant patient harm that's unnecessary.

Q And in your opinion, do you have an opinion as to whether or not the mechanical red flags that Mr. Catizone describes and then are applied by a computer program -- wait. Let me start over.

Do you have an opinion as to whether or not the mechanical red flags and the way that they're then applied through a computer program interrupt the flow of legitimate treatment of pain management?

MR. LANIER: Objection, Your Honor. Doesn't reflect testimony with the computer.

MR. MAJORAS: I'll switch, Your Honor.

THE COURT: All right.

BY MR. MAJORAS:

Q Your Honor -- Your Honor.

MR. MAJORAS: I'm not going to ask Your Honor any questions. Thank you.

THE COURT: Well, I'm not qualified to answer the ones that this doctor is answering, that's for sure.

MR. MAJORAS: I'm having trouble just forming a question. I don't have many answers.

BY MR. MAJORAS:

Q Dr. Wailes, in all seriousness, do you know who, I believe it was Dr. McCann, it might be Mr. McCann, is who testified earlier in this case?

A Yes.

Q And is it your understanding that what Mr. Catizone did was spell out what they thought the red flags were and then Mr. McCann, who I believe was described -- and I don't mean this negatively at all -- as a math geek, took those red flags and applied them across a group of prescriptions?

A That's my understanding, yes.

Q So using that method, whatever we want to call that, using that method, is it your -- do you have an opinion as to whether that method of identifying and searching for red flags will catch up legitimate prescriptions in that process?

A Yes, I do. My opinion is that he, through his harvesting of red flags, they caught approximately 20 percent of all opioid prescriptions reflect, and assuming that 99 percent of doctors are legitimate prescribing -- legitimately prescribing medication stuff, that is going to capture -- and we'll talk more details about it -- but that will capture a lot of legitimate prescriptions that don't

require full resolution or do not give.

Again, red flags by themselves are all right, but if they capture 20 percent, that means it's oversensitive. There's a lot of false positives.

16:56:20 **Q** What do you know by false positives?

A What I mean by that is that you're screening for something. His red flags screen for certain conditions. It might be a dosage. It might be the distance the patient traveled, and if those measures are overly sensitive, what

16:56:41 that means is they'll pick up a lot of normal situations. They'll pick up a lot of normal conditions, and those are false positives. So false in that they're called as a positive red flag, but they shouldn't be a red flag at all. And that's a false positive. And if -- if the measures you

16:57:00 have are too sensitive, if they pick up way too many patients, then it's not useful.

Q So would it be helpful to you in explaining what you just said by going through some examples as you look at the specific red flags that Mr. Catizone identified?

16:57:16 **A** Yes.

Q Okay. Let's go to slide 28, please.

Now, this is -- well, let me just ask you to explain.

What do you mean by dose thresholds and what you are describing this slide as it relates to Mr. Catizone's flags?

16:57:36 **A** So, what Mr. Catizone described as a red flag were the

dose of a medication in terms of morphine milliequivalents a day, morphine milligram equivalents a day. So that's the strength of how much opioid per day that you're getting.

And so what he did in this situation is he screened for certain amounts. Now, I need to say from the get-go that when he screened for these certain amounts, he didn't segregate out patients that had cancer. He didn't segregate out patients at end of life. He didn't segregate out patients that were on the same dose for the last three years that had chronic pain.

He applied these standards to a hundred percent of the prescriptions he reviewed, which were all patients. And -- I can go into how he came up with these numbers. They were based on -- and he states in his report, they were based on the CDC guidelines that were put out in 2016 for use by primary care doctors in chronic pain only. So he misapplied guidelines for the use of opioids, the doses of opioids, that were meant only to apply to primary care doctors for chronic pain, and those guidelines were not an absolute number at all. They were just suggested recommendations on how to prescribe. They were not meant to be weaponized as an absolute bright line not to exceed. That was not in the language of the CDC guidelines.

And also, those guidelines did not apply, specifically, to oncologists, end-of-life care, other types

of doctors. It was only specifically for primary care doctors and chronic pain.

Q So let's break that down a little bit if we could.

When the flags that he identifies talk about dose thresholds, they are triggered or flagged if certain upper limits of prescription are met; correct?

A That's correct.

Q Okay. You made it -- you distinguished in your answer the CDC guidelines or guidance as it related to primary care. Why does that matter to you? Tell us why that's important.

A Well, the only reason why it's important is he fell back on that document to create these numbers, and that's not appropriate because these numbers are being applied to every type of doctor and every type of pain. And so I use that because he used it as foundational for coming up with these numbers.

Q So, for example, you specifically said that he didn't call out patients with cancer and end-of-life care, and then I couldn't write notes as quickly beyond that.

Why do those types of patients matter when you're talking about pain -- I'm sorry -- dose thresholds?

A Very important to know that with acute pain, frequently you can get by with smaller doses, but it varies tremendously, but you can get by with smaller doses.

Most patients with cancer pain, it's usually severe, moderate to severe, and require large doses. Everyone in the medical field knows that by treating and being exposed to cancer patients. It can be devastating when the disease spreads to your bones and other parts of your body. And same with hospice, end-of-life care from non-cancer conditions, and certainly with complicated pain management conditions, they're going to require higher doses than what you would typically use for someone who's just starting treatment with opioids or someone who's just being treated for an acute pain.

Q Let's take a look at the CDC guideline that you talked about, and this is Exhibit DEF-MDL-05689.

Oh, got the wrong -- no, I'm sorry, that's correct.

MR. MAJORAS: So, first of all, Your Honor, just for recordkeeping purposes -- nope. We made the correction. I'm sorry, Your Honor.

BY MR. MAJORAS:

Q Okay. Dr. Wailes, back to you.

In terms of what you described to us as the guidelines about primary care clinicians, where do we find that in this document?

A On the very top it describes, in the verbiage there, in specific terms it says, for primary care providers treating adults 18 plus with chronic pain, greater than

three months, excluding cancer, palliative, and end-of-life care.

Q So even the CDC says those types of pain patients, the cancer, the palliative care, and end-of-life care wouldn't be part of this guideline; right?

17:02:59

A That's correct.

Q And if you -- if we could take that down, please, and we'll go to slide 30.

What are we seeing on slide 30 what you reference in your report?

17:03:41

A Yeah. That's a reprint of an article from the CDC trying to correct the misapplication of their guidelines to the medical profession and the public stating that many of their guidelines, including what we just heard about, were misapplied. They were not meant to be standards. They were not meant to be hard line thresholds not to exceed. And reading the text of the guidelines, you see that. And I'm sorry to say that Mr. Catizone did not use those guidelines as intended. He made it general for all -- all conditions and all prescriptions and applied that guideline to all of his prescriptions.

17:04:00

17:04:23

Q Let's move to another one of Mr. Catizone's flags.

You recall that his first and second flags related to distance traveled between the pharmacy or prescriber or the prescriber and the patient?

17:04:41

A Yes.

Q Okay. And if we go to slide 31, please. And we've seen testimony on this, but the distance he identifies is cut off as 25 miles.

17:04:55 Do you recall that?

A Yes, I do.

Q What's your reaction to that particular flag and how it could impact the treatment of -- appropriate treatment of pain management?

17:05:05 **A** In my experience and my understanding of multiple other practices that traveling 25 miles is not uncommon at all. Certainly from Lake and Trumbull Counties, it's over 25 miles to a number of facilities, including for most of Lake County, it would be to the Cleveland Clinic, or

17:05:28 University Hospital, certainly to University of Pittsburgh Medical Center.

It's very common to travel more than 25 miles. I think about how many of my workers commute more than 25 miles to work in my office. Likewise, patients travel

17:05:45 more than 25 miles to see their physician. One reason they may see their physicians while they're at work. Others, they may have to see a specialist. Others, they've moved recently and they want to stay with their doctors so they're willing to travel a little extra distance. So an arbitrary

17:06:04 25-mile distance would be exceeded numerous times.

Q Let's go to slide 34, please.

MR. MAJORAS: Your Honor, this part of the exam takes a little bit of time.

THE COURT: Yeah, I was going to -- I feel badly to cut off -- cut you and the doctor off in the middle, but I think it's -- if you're going through a number of these, if this is as good a time as any to stop, we should stop.

MR. MAJORAS: I think it's a good time, Your Honor.

THE COURT: All right.

Okay. Thank you.

Ladies and gentlemen, we will recess for the day. Usual admonitions apply. Do not read, watch, listen to anything you might encounter about this case or anything remotely like it in the media.

Do not discuss the case with anyone.

Have a good evening, and we'll pick up tomorrow morning at 9:00 with more of the doctor's testimony.

(Jury excused from courtroom at 5:07 p.m.)

THE COURT: Okay. Please be seated. If you just close the backdoor.

Doctor, you may be excused. Have a good evening, and I guess it's West Coast time, you can still do your president of the medical association business now.

THE WITNESS: Thank you.

(Witness excused.)

THE COURT: Okay. I don't know if anyone had gone through any of the exhibits for Ms. Toiga or Mr. Pavlich. If we've got those, fine. If not, we'll just put them off till tomorrow.

MS. FLEMING: Your Honor, this is Maria Fleming for plaintiffs.

Yes, we've already reviewed them. No objections to them.

THE COURT: All right. Well, we -- can I just -- I'll just read them in the record then. That's fine.

MS. FLEMING: Okay.

THE COURT: If we've got --

MS. FLEMING: It's the defendants' --

MR. DELINSKY: Do you want me to read them, Your Honor?

THE COURT: Sure. Mr. Delinsky, if you've got them. That's just as --

MR. DELINSKY: Sure.

It's Defendant MDL-11039, Defendant MDL-11038, Defendant MDL-12271, Defendant MDL-12071.

And the only caveat, Your Honor, is I got every one wrong yesterday, so I really am trying, but I think these

are right for Toiga.

THE COURT: Okay. Thank you.

All right. So we'll -- if you can, you know, overnight look at Mr. Pavlich, that's fine.

17:09:24 Okay.

MR. DELINSKY: And, Your Honor, am I correct for the record those are admitted?

THE COURT: Yeah, admitted without objection, those four. Thank you.

17:09:30 MR. DELINSKY: Thank you, Your Honor.

THE COURT: Okay. All right. I guess for today I had 1.25 for the plaintiffs and 5.25 for the defense.

When the -- Mr. Weinberger or Mr. Lanier, I know

17:09:48 you're going to be looking hard at that issue with distribution claims. I've looked at the jury instructions. The defendant -- the jury's not going to be asked to vote separately on claims at all. It's whether the defendants committed an intentional and/or illegal action that was a

17:10:06 significant cause of a public nuisance in Lake -- one set -- Trumbull.

Candidly, there has not been, my recollection, much, if any, testimony on illegal or improper orders, or red flags on orders, or -- I just don't recall much, you know,

17:10:34 testimony at all about orders per se. And as I pointed out

to everyone over a year ago, even if there are improper orders, unless it's coupled with improper dispensing, there can't be a harm because the drugs just stay in the pharmacy. All right?

17:10:53 So. . . it may make this trial shorter and simpler without distribution claims. So, again, if you disagree, then, you know, you'll file it, but I'm just -- I've given it a lot -- some thoughts since the defendants raised their motion, so. . .

17:11:12 Okay. Anything else that anyone wants to bring up? Obviously tomorrow we're, you know, however long it takes with this witness and then we'll keep going.

MR. MAJORAS: Your Honor, the only thing I will note, and I have not discussed this with the

17:11:26 plaintiffs' counsel yet, our second witness tomorrow, Dr. Murphy, is one that if -- if he goes through to the end of the day and there's carryover, we'll have to break it apart somewhat the way we did with Dr. Keyes, which seems --

THE COURT: It may be easier to do a bunch

17:11:43 of -- some videos --

MR. MAJORAS: We're going to look at that very closely, Your Honor.

THE COURT: All right. I mean, that's -- you know, again, particularly since there's a weekend, it may be

17:11:50 more coherent to just do some, you know, shorter depositions

even though I know people tend to glaze if you have multiple depositions.

MR. MAJORAS: These are fascinating, Your Honor.

17:12:03 THE COURT: Fair enough. But I -- you know, it may be better to do that than to break someone up over the weekend.

MR. MAJORAS: Thank you.

THE COURT: So you can work with the

17:12:13 plaintiffs on that.

MR. LANIER: Will you let us know tonight, please?

MR. MAJORAS: Yes.

MR. LANIER: Thank you.

17:12:17 THE COURT: Okay. Anything else?

Okay. Have a good evening, everyone.

COUNSEL EN MASSE: Thank you, Your Honor.

(Proceedings adjourned at 5:21 p.m.)

C E R T I F I C A T E

I certify that the foregoing is a correct transcript of the record of proceedings in the above-entitled matter prepared from my stenotype notes.

/s/ Heather K. Newman *10-28-2021*
HEATHER K. NEWMAN, RMR, CRR DATE